

SANUWAVE Health, Inc.

Form S-1/A

February 03, 2016

As filed with the Securities and Exchange Commission on February 3, 2016

Registration No. 333-208676

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other Jurisdiction of Incorporation
or Organization)

3841

(Primary Standard Industrial Classification
Code Number)

20-1176000

(I.R.S. Employer
Identification No.)

11475 Great Oaks Way, Suite 150

Alpharetta, Georgia 30022

(770) 419-7525

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Kevin A. Richardson, II

**Acting Chief Executive Officer
SANUWAVE Health, Inc.**

**11475 Great Oaks Way, Suite 150
Alpharetta, Georgia 30022
(770) 419-7525**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

David E. Danovitch, Esq.

Joseph E. Segilia, Esq.

**John C. Ethridge, Jr., Esq.
Smith, Gambrell & Russell, LLP
Promenade II, Suite 3100**

**Robinson Brog Leinwand Greene
Genovese & Gluck P.C.**

**1230 Peachtree Street, N.E.
Atlanta, Georgia 30309
(404) 815-3500**

**875 Third Avenue, 9th Floor
New York, NY 10022**

Telephone (212) 603-6300

Fax: (212) 956-2164

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration

statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered ⁽¹⁾	Amount to be registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Units ⁽²⁾⁽³⁾		\$ -	\$ 4,000,000	\$ 402.80
Common Stock, \$0.001 par value, included as part of the Units ⁽⁴⁾		\$ -	\$ -	\$ -
Warrants, included as part of the Units ⁽⁴⁾		\$ -	\$ -	\$ -
Common Stock Underlying Warrants ⁽³⁾⁽⁵⁾		\$ -	\$ -	\$ -
Common Stock, \$0.001 par value ⁽⁶⁾	19,887,836	\$ 0.08	\$ 1,591,027	\$ 160.22
Placement Agent's Warrants to acquire common stock		\$ -	\$ -	\$ -
Common Stock issuable upon exercise of the Placement Agent's Warrants		\$ -	\$ 400,000	\$ 40.28
Total ⁽⁷⁾	19,887,836			\$ 603.30

(1) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(2) Each "Unit" consists of one (1) share of common stock, \$0.001 par value and one (1) detachable warrant.

(3) Calculated pursuant to Rule 457(o) under the Securities Act on the basis of the maximum aggregate offering price of the securities being registered.

(4) No Registration Fee required pursuant to Rule 457(g).

(5) Calculated in accordance with Rule 457(g).

(6) Common Stock being registered for re-sale by selling shareholders. Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, based on the per share average of the high and low reported prices for the common stock on the Over the Counter Bulletin Board as of January 20, 2016.

(7) The Registrant previously paid a registration fee of \$492.42, and the registration fee due in connection with this filing is further offset by an additional \$920.43 of unused registration fees carried forward.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration

statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. Neither the Company, nor our selling stockholders, may sell the securities described herein until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell the securities and we are not soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus, Subject to Completion, Dated February 3, 2016.

Up to \$4,000,000

of

Units

(Common Stock, \$0.001 par value and Warrants)

\$889,993

of

Common Stock

Offered by Selling Stockholders

We are offering a minimum of 31,250,000 Units (the “Units”), with each Unit consisting of (i) one (1) share of our common stock, \$0.001 par value (the “Common Stock”) and, (ii) one (1) detachable warrant (the “Warrants”) to purchase one (1) share of our Common Stock at an exercise price of \$0.08 per share for gross proceeds of \$2,500,000 (the “Minimum Offering”) before deduction of commissions and offering expenses and a maximum of 50,000,000 Units for gross proceeds of \$4,000,000 (the “Maximum Offering”) before deduction of commissions and offering expenses. The Units will separate immediately and the Common Stock and Warrants will be issued separately. This offering expires on the earlier of (i) the date upon which all of the Units being offered have been sold, or (ii) February 19, 2016. In addition, we may terminate this offering at any time prior to the expiration date. All costs associated with the registration will be borne by us.

All funds sent to the Company to purchase the Units will be deposited in a non-interest bearing escrow account, maintained by Signature Bank (the “Escrow Agent”). Within three business days of receipt of the Minimum Offering amount in escrow the Company will first close on the subscription amounts in escrow as of such date subject to the

Maximum Offering amount, and additional closings may be held until the expiration or termination of the offering. If we do not sell and receive payments for the Minimum Offering amount prior to February 19, 2016, investor subscriptions will be returned without interest or deduction.

In addition, this prospectus relates to the sale of up to 19,887,836 outstanding shares of our Common Stock by the selling stockholders listed in this prospectus. The shares offered by this prospectus may be sold by the selling stockholders, from time to time, in the over-the-counter market or other national securities exchange or automated interdealer quotation system on which our Common Stock is then listed or quoted, through negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, or otherwise in compliance with the “Plan of Distribution” contained herein.

We will receive none of the proceeds from the sale of any shares by the selling stockholders. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

We have engaged Newport Coast Securities, Inc. to act as our exclusive placement agent in connection with this offering. We have agreed to pay the placement agent a cash fee of (i) ten percent (10%) of the aggregate purchase price of the Units sold in this offering and (ii) warrants to purchase ten percent (10%) of the number of shares sold in this offering. In the case of the Minimum Offering, 31,250,000 Units, the placement agent will be issued warrants to purchase 3,125,000 shares of Common Stock at an exercise price of \$0.08 per share and in the case of the Maximum Offering, 50,000,000 Units, the placement agent will be issued warrants to purchase 5,000,000 shares of Common Stock at an exercise price of \$0.08 per share. The registration statement of which this prospectus is a part also covers the placement agent’s warrants and the shares of Common Stock issuable from time to time upon the exercise of the placement agent’s warrants. The placement agent’s warrants and the underlying shares of Common Stock are subject to compliance with the requirements of the Financial Industry Regulatory Authority, Inc., or FINRA.

See “Plan of Distribution” beginning on page 26 of this prospectus for more information regarding the above compensation payable to the placement agent.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol SNWV.OB. The high and low bid prices for shares of our Common Stock on January 20, 2016, were \$0.09 and \$0.07 per share, respectively, based upon bids that represent prices quoted by broker-dealers on the OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 6 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Brokers or dealers effecting transactions in these securities should confirm that the securities are registered under the applicable state law or that an exemption from registration is available.

Placement Agent

Newport Coast Securities, Inc.

The date of this prospectus is _____, 2016

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PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary may not contain all of the information that you should consider before investing in our Common Stock. You should carefully read the entire prospectus, including “Risk Factors” and the consolidated financial statements, before making an investment decision.

Unless the context requires otherwise, the words “SANUWAVE,” “we,” “Company,” “us,” and “our” in this prospectus refer to SANUWAVE Health, Inc. and our subsidiaries.

About This Prospectus

You may rely only on the information contained in this prospectus or that we have referred you to. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

Our Company

We are a shockwave technology company using a patented system of noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the demaPACE[®] device, used for treating diabetic foot ulcers, which is in a supplemental Phase III clinical study with possible FDA approval in 2016, subject to submission of satisfactory clinical study results.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE[®]) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. We currently do not market any commercial

products for sale in the United States. We generate our revenues from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

In addition, we believe that there are license/partnership opportunities for the Company's shockwave technology for non-medical uses, including energy, water, food and industrial markets. For more information about the Company, see the section entitled "Business" in this prospectus.

Product Overview; Strategy

We are focused on developing our Pulsed Acoustic Cellular Expression (PACE) technology to activate healing in:

wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;
orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;
plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and
cardiac applications for removing plaque due to atherosclerosis and improving heart muscle performance.

In addition to healthcare uses, our high-energy, acoustic pressure shockwaves, due to their powerful pressure gradients and localized cavitation effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

We are focused on the development of regenerative medicine products that have the potential to address substantial unmet clinical needs across broad market indications. We believe there are limited therapeutic treatments currently available that directly and reproducibly activate healing processes in the areas in which we are focusing, particularly for wound care and repair of certain types of musculoskeletal conditions.

For more information about the Company, see the section entitled “Business” in this prospectus.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled “Risk Factors” immediately following this prospectus summary. We have a limited operating history and have incurred substantial losses since inception. We expect to continue to incur losses for the foreseeable future and are unable to predict the extent of future losses or when we will become profitable, if at all. Our products are in various stages of clinical trials and have not yet received regulatory approval in the United States. Our ability to generate revenue in the future will depend heavily on the successful development and commercialization of our product candidates. Even if we succeed in developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and sustain profitability. We may be unable to maintain and protect our intellectual property, which could have a substantial impact on our ability to generate revenue. Our products are subject to regulation by governmental authorities in the United States and in other countries. Failure to comply with such regulations or to receive the necessary approvals or clearances for our product and product candidates may have a material adverse effect on our business.

Trading Market

Our Common Stock, is quoted on the Over the Counter Bulletin Board under the symbol “SNWV.OB.”

Corporate Information

We were incorporated in the State of Nevada on May 6, 2004, under the name Rub Music Enterprises, Inc. (“RME”). SANUWAVE, Inc. was incorporated in the State of Delaware on July 21, 2005. In December 2006, Rub Music Enterprises, Inc. ceased operations and became a shell corporation.

On September 25, 2009, RME and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of RME (the “*Merger Sub*”) entered into a reverse merger agreement with SANUWAVE, Inc. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, Inc., with SANUWAVE, Inc. as the surviving entity (the “*Merger*”) and a wholly-owned subsidiary of the Company.

In November 2009, we changed our name to SANUWAVE Health, Inc. Our principal executive offices are located at 11475 Great Oaks Way, Suite 150, Alpharetta, Georgia 30022, and our telephone number is (770) 419-7525. Our website address is www.sanuwave.com. The information on our website is not a part of this prospectus.

About this Offering

Securities being offered by the Company

<i>Securities being offered by us</i>	In the case of the Minimum Offering, 31,250,000 Units, each Unit consisting of one (1) share of Common Stock and one (1) Warrant to purchase one (1) share of Common Stock at an exercise price of \$0.08 per share. In the case of the Maximum Offering, 50,000,000 Units.
<i>Offering price</i>	\$0.08 per Unit.
<i>Description of Warrants</i>	The warrants will be exercisable at any time during the period commencing on the date of closing of the offering and ending on March 17, 2019 at an exercise price per share equal to \$0.08.
<i>Shares of Common Stock that may be issued upon the exercise of Warrants issued as part of the Units</i>	In the case of the Minimum Offering, 31,250,000 shares of Common Stock. In the case of the Maximum Offering, 50,000,000 shares of Common Stock.
<i>Use of proceeds</i>	We intend to use the net proceeds from the sale of Units by us primarily for expenses related to the Premarket Approval (PMA) submission to the FDA of dermaPACE for treating diabetic foot ulcers in the United States, commercialization of dermaPACE in the United States and for other general corporate purposes.
<i>Expiration time/date</i>	February 19, 2016
<i>Shares of Common Stock outstanding before this offering</i>	70,504,473 shares ⁽¹⁾
<i>Shares of Common Stock to be outstanding after this offering</i>	In the case of the Minimum Offering, 94,306,519 (125,556,519 shares if the Warrants are exercised in full) of Common Stock. In the case of the Maximum Offering, 113,056,519 (163,056,519 shares if the Warrants are exercised in full) of Common Stock.
<i>Escrow</i>	All funds sent to the Company to purchase the Units will be deposited in a non-interest bearing escrow account, maintained by Signature Bank (the "Escrow Agent") at a bank account at the branch of Signature bank selected by the Escrow Agent. Within three business days of receipt of the Minimum Offering amount in escrow the Company will first close on the subscription amounts in escrow as of such date subject to the Maximum Offering amount, and additional closings may be held until the expiration or termination of the offering. If we do not

sell and receive payments for the Minimum Offering amount prior to February 19, 2016, investor subscriptions will be returned without interest or deduction.

Subscription Procedures

Investors interested in subscribing for the Units in this offering must complete and deliver to the Placement Agent a completed subscription agreement to the address provided in the subscription agreement and deliver the purchase price by wire transfer in immediately available funds using the wire transfer instructions provided in the subscription agreement. Funds and subscription documents will be held in escrow until the first closing of this offering at which time the escrowed funds and subscription documents will be released by the Escrow Agent. Promptly following the first closing the Units purchased by the investor in the offering will be issued to the investor. If this offering is not completed for any reason all proceeds deposited into escrow will be returned to the investor without interest or deduction.

OTC Bulletin Board market symbol

SNWV

Risk factors

See “Risk Factors” beginning on page 5 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Common Stock.

Securities being offered by the Selling Stockholders

*Common
Stock* 19,887,836 shares.

*Use of
Proceeds* We will not receive any of the proceeds from the sale of the shares by the selling stockholders.

Risk Factors See “Risk Factors” beginning on page 6 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Common Stock.

⁽¹⁾ The number of shares shown to be outstanding is based on the number of shares of our Common Stock outstanding as of January 20, 2016, and does not include shares reserved for issuance upon the exercise of warrants outstanding, or options granted or available under our equity compensation plans.

SUMMARY FINANCIAL INFORMATION

The summary financial information set forth below is derived from and should be read in conjunction with our consolidated financial statements, including the notes thereto, appearing at the end of this prospectus.

Nine Months Ended September 30,	Year Ended
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