SANUWAVE Health, Inc.
Form S-1/A
July 01, 2013

As filed with the Securities and Exchange Commission on July 1, 2013
Registration No. 333-187625

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 3
To
FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITES ACT OF 1933

SANUWAVE Health, Inc.
(Exact name of registrant as specified in its charter)

Nevada	3841	20-1176000
(State or other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(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)

Joseph Chiarelli
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:
John C. Ethridge, Jr., Esq.
Smith, Gambrell & Russell, LLP
Promenade, Suite 3100
1230 Peachtree Street, N.E.
Atlanta, Georgia 30309
(404) 815-3500

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: x

If this Form is filed to registered 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. o

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. o

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. o

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 o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x

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. We may not sell these securities described herein until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary 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 July 1, 2013

Up to 10,909,091 Units, each Unit consisting of one share of common stock and a warrant to purchase up to an additional 1/2 share of common stock

We are offering up to 10,909,091 Units at a purchase price of $0.55 per Unit, with each Unit consisting of one share of our common stock and a warrant to purchase up to an additional 1/2 share of our common stock at an exercise price per share of $0.80. The Units will not be certificated and the common stock and warrants will be immediately separable and will be separately transferable immediately upon issuance. The securities are being offered on a "best efforts" basis, and we are not required to sell any specific dollar amount or number of Units. The offering expires on the earlier of (i) the date upon which all of the Units being offered have been sold, or (ii) July 31, 2013. In addition, we may terminate the offering at any time prior to the expiration date. All costs associated with the registration will be borne by us.

Our common stock is quoted on the OTC Bulletin Board under the symbol "SNWV". The last reported sale price of our common stock on June 28, 2013 on the OTC Bulletin Board was $0.67 per share. There is no established trading market for the warrants.

	Per Unit	Total
Offering Price per Unit	$0.550	$ 6,000,000
Placement Agent's Fees (1)	$ 0.044	$ 480,000
Offering Proceeds, before expenses	$ 0.506	$ 5,520,000

1). See "Plan of Distribution" beginning on page 29 of this prospectus for more information on the placement agent fees

CIM Securities, LLC has agreed to act as our placement agent in connection with this offering, and CIM Securities, LLC is deemed an underwriter.

The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of securities, but will assist us in this offering on a "best efforts" basis. In addition, the placement agent may engage one or more sub-placement agents or selected dealers. We have agreed to pay the placement agent a cash fee equal to 8.0% of the gross proceeds of the offering of securities by us. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately $78,500. Because there is no minimum offering amount required as a condition to closing this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amount set forth above. See "Plan of Distribution" beginning on page 29 of this prospectus for more information on this offering and the placement agent arrangements.

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 determined if this prospectus is truthful or complete. 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.

CIM Securities, LLC

The date of this prospectus is _____, 2013

TABLE OF CONTENTS

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 SANUWAVE Health, Inc. and our wholly-owned subsidiary SANUWAVE, Inc.

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 solicit 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 dermaPACE® device, used for treating diabetic foot ulcers, which is in a supplemental Phase III clinical study with possible FDA approval in 2015 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 are not marketing any commercial products in the United States. We generate our revenues from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada and Asia/Pacific.

In addition, we believe there are significant license/partnership opportunities for our shockwave technology in non-medical uses, including energy, food and industrial markets, and we believe we have a broad intellectual property portfolio and broad know-how.

Product Overview

Pulsed Acoustic Cellular Expression (PACE) Technology for regenerative medicine

We believe we have demonstrated that our technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe and Asia. Our lead product candidate for

the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

1

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

- wound conditions, including diabetic foot ulcers, venous ulcers, pressure sores, burns and other skin eruption conditions;
- orthopedic applications, such as eliminating chronic pain in joints from trauma or arthritis, 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.

dermaPACE – Our lead product candidate

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. We have identified and contracted with clinical study sites for participation in the clinical study. We held the investigator meeting for protocol training on May 10-11, 2013 and patient enrollment began in June 2013 with eleven patients enrolled as of June 28, 2013.

The dermaPACE device completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA Application was filed with the FDA in June 2011. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. In December 2011, we received a major deficiency letter from the FDA regarding the FDA's review of the dermaPACE PMA. The FDA issues a major deficiency letter to the applicant when the PMA lacks significant information necessary for the FDA to complete its review or to determine whether there is reasonable assurance that the device is safe and effective for its intended use.

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's failure to meet the study's primary endpoint of 100% wound closure compared with sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency was for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we decided to conduct supplemental clinical work as discussed above.

Non-medical uses for our shockwave technology

In addition to healthcare uses, our high-energy, acoustic pressure shockwaves, due to their powerful pressure gradients and localized cavitational 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. We intend to seek to exploit such potential uses through licensing and/or partnership opportunities.

Strategy

Our objective is to be a leader in the development and commercialization of our shockwave technology, which utilizes a patented system of noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other non-medical applications. The key elements of our strategy include the following:

- Obtain FDA approval for our dermaPACE device to treat diabetic foot ulcers.

Our initial focus is obtaining FDA approval for our lead product candidate, dermaPACE, for the wound care market, initially in the United States for diabetic foot ulcers, which we believe represents a large, unmet need. The FDA has granted approval of our IDE Supplement to conduct a clinical trial utilizing the dermaPACE device in the treatment of diabetic foot ulcers. We have identified and entered into contracts with clinical study sites. Patient enrollment began in June 2013 with eleven patients enrolled as of June 28, 2013.

- Develop and commercialize our noninvasive biological response activating devices in the regenerative medicine area for the treatment of tissue, musculoskeletal and vascular structures.

We intend to use our proprietary technologies and know-how in the use of high-energy, acoustic pressure waves in the shockwave spectrum to address unmet medical needs in wound care, orthopedic, plastic/cosmetic and cardiac indications, possibly through potential license and/or partnership arrangements.

- License and seek partnership opportunities for our non-medical shockwave technology platform, know-how and extensive patent portfolio.

We intend to use our shockwave technology and know-how for non-medical uses, including energy, food, water and industrial markets, through license/partnership opportunities.

- Support the global distribution of our products.

Our portfolio of products, the dermaPACE and orthoPACE, are CE Marked and sold through select distributors in certain countries in Europe, Canada and Asia/Pacific. Our revenues are from sales of the devices and related applicators in these markets. We currently do not market any commercial products in the United States. We intend to continue to add additional distribution partners in Europe and Asia/Pacific.

Liquidity and Capital Resources

The continuation of our business is dependent upon raising additional capital in the second quarter of 2013. As of March 31, 2013, we had cash and cash equivalents of $671,027 and negative working capital of $7,130,480 (which includes $5,737,000 for a non-cash derivative liability for the embedded conversion feature of the senior secured notes). For the three months ended March 31, 2013 and 2012, the net cash used by operating activities was $1,043,674 and $1,490,445, respectively. We incurred a net loss of $5,369,333 for the three months ended March 31, 2013 and a net loss of $6,401,494 for the year ended December 31, 2012. Since inception, we have experienced recurring losses from operations and had an accumulated deficit of $76,279,655 at March 31, 2013. As a result, our auditors have raised substantial doubts as to our ability to continue as a going concern.

On March 8, 2013, we completed a private placement to accredited investors of an aggregate $2,000,000 of 18% Senior Secured Convertible Promissory Notes (Senior Secured Notes). The Senior Secured Notes were initially to begin to mature in May 2013 and have been amended to extend the maturity date to July 31, 2013. The Senior Secured Notes, as amended, will automatically convert to common stock if we raise $4,000,000 or more in gross proceeds through a qualified financing (such as in this offering) and/or license agreement as defined in the Senior Secured Note agreements. If we do not raise at least $4,000,000, or amend the agreements, the Senior Secured Notes will not automatically convert to common stock and will become due and payable.

We have raised $300,000 through the issuance of unsecured promissory notes in May and June 2013. When combined with our cash and cash equivalents as of March 31, 2013 of $671,027, and amounts which can be received, if necessary, through a subscription agreement with an affiliated shareholder, we believe this will support our operations into July 2013 and the expected completion of this offering. We expect our monthly use of cash will be approximately $575,000 to $625,000 as we devote substantial resources to the start of the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers by the end of the second quarter of 2013. We estimate the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

Even if we sell all of the Units offered in this offering, we will require additional capital to support the dermaPACE clinical trial and continue our operations within the next twelve months. Such additional capital may not be available on terms that are favorable to us, if at all. If we are unable to raise such additional funds, we may be forced to cease operations.

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. Our wholly-owned subsidiary, SANUWAVE, Inc., which we acquired in a reverse merger transaction in September 2009, was incorporated in the State of Delaware on July 21, 2005. 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 us	10,909,091 Units, each Unit consisting of one share of common stock and one warrant to purchase 1/2 share of common stock at an exercise price per share of $0.80.
Offering price	$0.55 per Unit.
Description of Warrants	The warrants will be exercisable at any time during the period commencing on the date of closing of the offering and ending on the fifth anniversary of the closing of the offering at an exercise price per share of $0.80.

4

Shares of common stock that may be issued upon the exercise of warrants issued as part of the Units	5,454,545 shares of common stock.
Use of proceeds	We intend to use the net proceeds from the sale of Units in this offering primarily for expenses related to our dermaPACE clinical trial for treating diabetic foot ulcers in the United States and for other general corporate purposes. We have outstanding an aggregate $2,157,500 in principal and accrued interest on our 18% Senior Secured Convertible Promissory Notes, as amended (Senior Secured Notes), which begin to mature on July 11, 2013 for certain of the noteholders. Subject to the condition that we raise at least $4,000,000 in gross proceeds through this offering, the Senior Secured Notes will automatically convert into (i) common stock at a conversion price of $0.20, and (ii) warrants to purchase the number of shares of common stock equal to the number of shares such holder would have received if it had invested in the offering an amount equal to the principal and interest on the note being converted. If we do not raise at least $4,000,000 in gross proceeds through this offering, or amend the agreements, the Senior Secured Notes will not automatically convert to common stock and they will become due and payable and we may use all or part of any net proceeds from this offering towards repayment of the Senior Secured Notes. See “Use of Proceeds” and “Description of Securities”. In addition, we may use part of the proceeds from this offering toward the repayment of the unsecured promissory notes issued in May and June of 2013, in the aggregate principal amount of $300,000, which begin to mature in November 2013. See “Use of Proceeds”.
Expiration time/date	July 31, 2013.
Common stock outstanding:	
Before the offering	21,907,870 shares.
After the offering	43,604,461 shares (includes 10,787,500 shares to be issued upon conversion of the Senior Secured Notes, assuming that at least $4,000,000 is raised in this offering).
OTC Bulletin Board market symbol	SNWV.
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.

The number of shares of our common stock to be outstanding after completion of this offering is based on 21,907,870 shares outstanding as of June 28, 2013 and assumes the sale of all Units offered in this offering and conversion of outstanding convertible notes in the aggregate amount of $2,157,500, convertible into 10,787,500 shares of common stock at a weighted average conversion price of $0.20, but does not include any shares issuable upon exercise of the warrants offered. The number of shares shown to be outstanding does not include shares reserved for issuance upon the (i) exercise of outstanding warrants to purchase 7,789,991 shares of common stock with a weighted average exercise price of $3.63, or (ii) exercise of outstanding options to purchase 8,279,330 shares of common stock with a weighted average exercise price of $1.14.

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.

	Three Months Ended		Year Ended	
	March 31, 2013 (Unaudited)	March 31, 2012 (Unaudited)	December 31, 2012	December 31, 2011
Consolidated Statement of Operations Data				