SANUWAVE Health, Inc.
Form 424B3
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Registration No. 333-195263

PROSPECTUS

56,793,600 Shares

Common Stock

This prospectus relates to the sale of up to 56,793,600 shares of our common stock. $0.001 par value (the "Common Stock") by the selling stockholders listed in this prospectus. These shares consist of 6,210,000 outstanding shares of Common Stock, 12,350,000 shares of Common Stock issuable upon conversion of the Series A Convertible Preferred Stock and 38,233,600 shares of Common Stock issuable upon the exercise of the warrants. 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 are registering these shares following our March 2014 private placement. We will receive none of the proceeds from the sale of the shares by the selling stockholders. We may receive proceeds upon the exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. 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.

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 April 25, 2014, were $0.65 and $0.62 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.

An investment in these securities involves a high degree of risk.

Please carefully review the section titled "Risk Factors" beginning on page 6.

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.

The date of this prospectus is May 7, 2014

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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.

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 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 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.

Product Overview

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a supplemental clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. Patient enrollment began in June 2013 and we have enrolled over 90% of the minimum number of ninety patients in the clinical trial. Management expects to complete the minimum enrollment phase of the clinical study early in the second quarter of 2014 with patient follow-up for efficacy twelve weeks thereafter. Assuming positive clinical results, we will then submit the PMA to the FDA with expected FDA approval in 2015.

We believe we have demonstrated that our patented 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.

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 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. Our business approach will be through licensing and/or partnership opportunities.

Market Trends

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.

According to AdvaMed and Centers for Medicare & Medicaid Services data and our internal projections, the United States advanced wound healing market for the dermaPACE is estimated at $5 billion, which includes diabetic foot ulcers, pressure sores, burns and traumatic wounds, and chronic mixed leg ulcers. We also believe there are significant opportunities in the worldwide orthopedic and spine markets, driven by aging baby boomers and their desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

With the success of negative pressure wound therapy devices in the wound care market over the last decade and the recognition of the global epidemic associated with certain types of wounds, as well as deteriorating musculoskeletal conditions attributed to various disease states such as obesity, diabetes and ischemia due to vascular and heart disease, as well as sports injuries, we believe that Medicare and private insurers have become aware of the costs and expenditures associated with the adjunctive therapies being utilized for wound healing and orthopedic conditions with limited efficacies in full skin closure, or bone and tissue regeneration. We believe the wound healing and orthopedic markets are undergoing a transition, and market participants are interested in biological response activating devices that are applied noninvasively and seek to activate the body’s own capabilities for regeneration of tissue at injury sites in a cost-effective manner.

Strategy

Our primary objective is to be a leader in the development and commercialization of our shockwave technology, which utilizes 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 dermaPACE device for treating diabetic foot ulcers, which is in a final 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.

Our immediate goal for our regenerative medicine technology involves leveraging the knowledge we gained from our existing human heel and elbow indications to enter the advanced wound care market with innovative treatments.

The key elements of our strategy include the following:

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

We are focusing initially on 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 supplemental clinical trial of the dermaPACE device in the treatment of diabetic foot ulcers. Patient enrollment began in June 2013 and we have enrolled over 90% of the minimum number of ninety patients in the clinical trial. Management expects to complete the minimum enrollment phase of the clinical study early in the second quarter of 2014 with patient follow-up for efficacy twelve weeks thereafter. Assuming positive clinical results, we will then submit the PMA to the FDA with expected FDA approval in 2015.

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, Asia and Asia/Pacific. Our revenues are from sales of the devices and related applicators in these markets. We currently do not have any commercial products available for sale in the United States. We intend to continue to add additional distribution partners in Europe and Asia/Pacific.

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, $.001 par value (the "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 (678) 581-6843. Our website address is *www.sanuwave.com*. The information on our website is not a part of this prospectus.

Unless the context requires otherwise, the words ““SANUWAVE,’’ ““we,’’ ““Company,’’ ““us,’’ and ““our’’ in this prospectu
SANUWAVE Health, Inc.

About this Offering

This prospectus relates to the public offering, which is not being underwritten, of up to 56,793,600 shares of our Common Stock by the selling stockholders listed in this prospectus. These shares consist of 6,210,000 outstanding shares of Common Stock, 12,350,000 shares of Common Stock issuable upon conversion of our Series A Convertible Preferred Stock and 32,233,600 shares of Common Stock issuable upon the exercise of the warrants. 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. We will receive none of the proceeds from the sale of the shares by the selling stockholders. We may receive proceeds upon exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. 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.

The shares of Common Stock being offered by this prospectus relate to shares of Common Stock, Series A Convertible Preferred Stock and warrants issued in our March 2014 private placement to ten accredited investors of 6,210,000 shares of our Common Stock and 6,175 shares of our Series A Convertible Preferred stock at a purchase price of $0.50 per unit, for gross proceeds to the Company of $9,280,000. The Series A Convertible Preferred Stock is convertible into 2,000 shares of Common Stock at the option of the holders. The net proceeds to the Company were $8,562,500, net of offering costs of $717,500. As part of the private placement, the investors were issued: (i) five-year warrants to purchase up to 23,200,000 shares of our Common Stock at an initial exercise price of $0.50 per share; and (ii) one-year warrants to purchase up to 13,920,000 shares of our Common Stock at an initial exercise price of $1.50 per share. The placement agent for the private placement and the former placement agent were issued in the aggregate: (i) five-year warrants to purchase up to 696,000 shares of our Common Stock at an initial exercise price of $0.50 per share; and (ii) one-year warrants to purchase up to 417,600 shares of our Common Stock at an initial exercise price of $1.50 per share. For a more detailed discussion regarding the private placement, please see “Selling Stockholders – March 2014 Private Placement” in this prospectus.

THE OFFERING

Common Stock being offered by the selling stockholders:

Shares of Common Stock	6,210,000 shares
Shares of Common Stock that may be issued upon conversion of the Series A Convertible Preferred Stock	12,350,000 shares
Shares of Common Stock that may be issued upon the exercise of the warrants	38,233,600 shares
Total	56,793,600 shares
Common Stock outstanding	46,966,519 shares (1)
OTC Bulletin Board symbol	SNWV.OB
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares by the selling stockholders, except cash for the warrant exercise price upon exercise of the warrants, which if such warrants are exercised in full for cash, would be approximately $33,454,400. Proceeds, if any, received from the exercise of such warrants, would be used for working capital purposes.
Risk Factors	See “Risk Factors” beginning on page 6 and other information included in this prospectus for a discussion of factors you should consider before investing in shares of 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 April 25, 2014, 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.

	Year Ended December 31, 2013	December 31, 2012
Consolidated Statement of Operations Data		
Revenue	$ 800,029	$ 769,217
Net loss	$ (11,299,721)	$ (6,401,494)
Weighted average shares outstanding	28,132,134	20,915,869
Net loss per share - basic and diluted	$ (0.40)	$ (0.30)
Consolidated Balance Sheet Data (at end of period)		
Working capital (deficit)	$ (1,700,118)	$ (2,413,536)
Total assets	$ 1,588,057	$ 1,850,536
Total liabilities	$ 7,715,938	$ 8,369,541
Total stockholders' deficit	$ (6,127,881)	$ (6,519,005)

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus, including the consolidated financial statements and the related notes appearing at the end of this prospectus, before purchasing our Common Stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In any such event, the market price of our Common Stock could decline and you could lose all or part of your investment.

Risks Related to our Business

We generate only minimal revenues and we continue to experience operating losses.

Since our inception, we have experienced recurring losses from operations. As of December 31, 2013, we had an accumulated deficit of $82,210,043. We generate only minimal revenues and we continue to experience operating losses. We anticipate that our operating losses will continue and we will continue to incur losses in future periods unless and until we are successful in significantly increasing our revenues and cash flow. There are no assurances that we will be able to increase our revenues and cash flow to a level which supports profitable operations and provides sufficient funds to pay our obligations.

We will be required to raise additional funds to finance the commercialization of the dermaPACE, assuming positive clinical results and FDA approval in 2015; we may not be able to do so, and/or the terms of any financings may not be advantageous to us.

The continuation of our business is dependent upon raising additional capital. Subsequent to year-end, on March 17, 2014, we completed a private offering of securities for an aggregate total purchase price of $9,280,000. As of December 31, 2013, we had cash and cash equivalents of $182,315 and negative working capital of $1,700,118. For the years ended December 31, 2013 and 2012, our net cash used by operating activities was $3,924,204 and $4,290,121, respectively. We need additional financial support for the commercialization of the dermaPACE, assuming positive clinical results and FDA approval in 2015, which may include: raising additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, an investment by a strategic partner in a specific clinical indication or market opportunity; or selling all or a portion of our assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. We will require additional capital to support development and continue our operations. 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.

We have a history of losses and we may continue to incur losses and may not achieve or maintain profitability.

For the year ended December 31, 2013, we had a net loss of $11,299,721 and used $3,924,204 of cash in operations. For the year ended December 31, 2012, we had a net loss of $6,401,494 and used $4,290,121 of cash in operations. As of December 31, 2013, we had an accumulated deficit of $82,210,043 and a total stockholders' deficit of $6,127,881. As a result of our significant research, clinical development, regulatory compliance and general and administrative expenses, we expect to incur losses as we continue to incur expenses related to seeking FDA approval for our dermaPACE device. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenues and we may never achieve or be able to maintain profitability.

If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long term viability may be threatened; however, if we do raise additional capital, your percentage ownership as a shareholder could decrease and constraints could be placed on the operations of our business.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our capital stock, the issuance of convertible promissory notes, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009 and product sales. We will seek to obtain additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. These financings could result in substantial dilution to the holders of our common stock, or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

A variety of factors could impact our need to raise additional capital, the timing of any required financings and the amount of such financings. Factors that may cause our future capital requirements to be greater than anticipated or could accelerate our need for funds include, without limitation:

- unforeseen developments during our clinical trials;
- delays in timing of receipt of required regulatory approvals;
- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of any approved product;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using any of our approved products;
- inability to train a sufficient number of physicians to create a demand for any of our approved products;

lack of financial resources to adequately support our operations;
difficulties in maintaining commercial scale manufacturing capacity and capability;
unforeseen problems with our third party manufacturers, service providers or specialty suppliers of certain raw materials;
unanticipated difficulties in operating in international markets;
unanticipated financial resources needed to respond to technological changes and increased competition;
unforeseen problems in attracting and retaining qualified personnel;
enactment of new legislation or administrative regulations;
the application to our business of new court decisions and regulatory interpretations;
claims that might be brought in excess of our insurance coverage;
the failure to comply with regulatory guidelines; and