SANUWAVE Health, Inc.
Form 424B3
March 18, 2016
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File No. 333-208676

PROSPECTUS

Up to $4,000,000

of

Units

(Common Stock, $0.001 par value and Warrants)

$1,883,609

of

Common Stock

Offered by Selling Stockholders

We are offering a minimum of 25,000,000 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 $1,500,000 (the "*Minimum Offering*") before deduction of commissions and offering expenses and a maximum of 66,666,667 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) March 31, 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 March 31, 2016, investor

subscriptions will be returned without interest or deduction.

In addition, this prospectus relates to the sale of up to 23,545,114 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, 25,000,000 Units, the placement agent will be issued warrants to purchase 2,500,000 shares of Common Stock at an exercise price of $0.08 per share and in the case of the Maximum Offering, 66,666,667 Units, the placement agent will be issued warrants to purchase 6,666,667 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 February 12, 2016, were $0.08 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 March 11, 2016

TABLE OF CONTENTS

-1-

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 re 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 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.

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

Securities being offered by us	In the case of the Minimum Offering, 25,000,000 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, 66,666,667 Units.
Offering price	$0.06 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 March 17, 2019 at an exercise price per share equal to $0.08.
Shares of Common Stock that may be issued upon the exercise of Warrants issued as part of the Units	In the case of the Minimum Offering, 25,000,000 shares of Common Stock. In the case of the Maximum Offering, 66,666,667 shares of Common Stock.
Use of proceeds	We intend to use the net proceeds from the sale of Units by us to pay down the HealthTronics debt as required by the amendment in the amount of 20% of the net proceeds of the offering and 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.
Expiration time/date	March 31, 2016
Shares of Common Stock outstanding before this offering	70,504,473 shares[(1)]

Shares of Common Stock to be outstanding after this offering	In the case of the Minimum Offering, 95,504,473 (120,504,473 shares if the Warrants are exercised in full) of Common Stock. In the case of the Maximum Offering, 137,171,140 (203,837,807 shares if the Warrants are exercised in full) of Common Stock.
Escrow	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 March 31, 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 6 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	23,545,114 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 February 12, 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		Year Ended	
	September 30, 2015	September 30, 2014	December 31, 2014	December 31, 2013
Consolidated Statement of Operations Data				
Revenue	$594,040	$610,705	$847,367	$800,029
Net loss	$(3,707,492)	$(5,750,509)	$(5,974,080)	$(11,299,721)
Weighted average shares outstanding	63,014,763	46,258,912	48,212,910	28,132,134
Net loss per share - basic and diluted	$(0.06)	$(0.12)	$(0.12)	$(0.40)
Consolidated Balance Sheet Data (at end of period)				
Working capital deficit	$(183,596)	$(1,131,755)	$(2,183,859)	$(1,700,118)
Total assets	$1,500,743	$5,912,688	$4,666,355	$1,588,057
Total liabilities	$6,627,081	$6,334,199	$6,217,755	$7,715,938
Total stockholders' deficit	$(5,126,338)	$(421,511)	$(1,551,400)	$(6,127,881)

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 September 30, 2015, we had an accumulated deficit of $91,891,615. 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 FDA approval in 2016; 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. At September 30, 2015, we had cash and cash equivalents totaling $625,450. For the nine months ended September 30, 2015 and 2014, the net cash used by operating activities was $3,007,790 and $5,542,192, respectively. For the years ended December 31, 2014 and 2013, our net cash used by operating activities was $6,678,369 and $3,924,204, respectively. We need additional financial support for the commercialization of the dermaPACE, assuming FDA approval in 2016, 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 nine months ended September 30, 2015, we had a net loss of $3,707,492 and used $3,007,790 of cash in operations. For the year ended December 31, 2014, we had a net loss of $5,974,080 and used $6,678,369 of cash in operations. 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. As of September 30, 2015, we had an accumulated deficit of $91,891,615 and a total stockholders' deficit of $5,126,338. 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
the uncertainty in industry demand and patient wellness behavior.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

We are no longer able to rely on Prides Capital Partners, LLC and NightWatch Capital LLC for financial support, and as a result must rely on third parties for financing.

In the past, we have relied on Prides Capital Partners, LLC (together with its affiliates, "*Prides Capital*") and NightWatch Capital LLC (together with its affiliates, "*NightWatch Capital*") for the ongoing financial support necessary to operate our business. At the time of this prospectus, both Prides Capital and NightWatch Capital have liquidated or are in the process of doing so, and they will not provide us with any additional financing or financial support in the future. To the extent we must obtain financing to support our cash needs, we will be entirely reliant on unrelated third parties. We do not have any lines of credit or other financing arrangements in place with banks or other financial institutions. We will require additional financing in the future, and additional financing may not be available at times, in amounts or on terms acceptable to us, or at all, which would have a material adverse effect on our business.

Our product candidates may not be developed or commercialized successfully.

Our product candidates are based on a technology that has not been used previously in the manner we propose and must compete with more established treatments currently accepted as the standards of care. Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use.

We are subject to the risks that:

- the FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates.

In addition, our product development program may be curtailed, redirected, eliminated or delayed at any time for many reasons, including:

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;
- the inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our trials; and
- regulatory delays or other regulatory actions.

We cannot predict whether we will successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

The medical device/therapeutic product industries are highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer and more effective than any products we may develop, our commercial opportunities will be reduced or eliminated.

Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products. We face competition from established medical device, pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies, and private and public research institutions in the United States and abroad. Many of our principal competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements, or mergers with, or acquisitions by, large and established companies, or through the development of novel products and technologies.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may develop and commercialize pharmaceutical, biotechnology or medical devices that are safer or more effective, have fewer side effects or are less expensive than any products that we may develop. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to our programs or advantageous to our business.

If our products and product candidates do not gain market acceptance among physicians, patients and the medical community, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates, they may not gain market acceptance among physicians, healthcare payers, patients and the medical community. Market acceptance will depend on our ability to demonstrate the benefits of our approved products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness. In addition, we believe market acceptance depends on the effectiveness of our marketing strategy, the pricing of our approved products and the reimbursement policies of government and third party payers. Physicians may not utilize our approved products for a variety of reasons and patients may determine for any reason that our product is not useful to them. If any of our approved products fail to achieve market acceptance, our ability to generate revenues will be limited.

We may not successfully establish and maintain licensing and/or partnership arrangements for our technology for non-medical uses, which could adversely affect our ability to develop and commercialize our non-medical technology.

Our strategy for the development, testing, manufacturing and commercialization of our technology for non-medical uses generally relies on establishing and maintaining collaborations with licensors and other third parties. We may not be able to obtain, maintain or expand these or other licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to obtain, maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to obtain, maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our technology for non-medical uses.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our technology for non-medical uses, including possibly the design and manufacture of product materials, potentially the obtaining of regulatory approvals and the marketing and distribution of any successfully developed products. Our collaborators also may have or acquire rights to control aspects of our product development programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we may contemplate. In addition, if any of these collaborators withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

We currently purchase most of our product component materials from single suppliers. If we are unable to obtain product component materials and other products from our suppliers that we depend on for our operations, or find suitable replacement suppliers, our ability to deliver our products to market will likely be impeded, which could have a material adverse effect on us.

We depend on suppliers for product component materials and other components that are subject to stringent regulatory requirements. We currently purchase most of our product component materials from single suppliers and the loss of any of these suppliers could result in a disruption in our production. If this were to occur, it may be difficult to arrange a replacement supplier because certain of these materials may only be available from one or a limited number of sources. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. In addition, establishing additional or replacement suppliers for these materials may take a substantial period of time, as certain of these suppliers must be approved by regulatory authorities.

If we are unable to secure, on a timely basis, sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then the manufacturing of our products may be disrupted, which could increase our costs and have a material adverse effect on our business and results of operations.

The loss of our key management would likely hinder our ability to execute our business plan.

As a small company with seven employees, our success depends on the continuing contributions of our management team and qualified personnel. Our success depends in large part on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical, biotechnology and medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

We face an inherent risk of liability in the event that the use or misuse of our product candidates results in personal injury or death.

The use of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims which could result in financial loss. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts or scope, to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management team and

other resources, and adversely impact or eliminate the prospects for commercialization of the product candidate, or sale of the product, which is the subject of any such claim. Although we do not promote any off-label use, off-label uses of products are common and the FDA does not regulate a physician's choice of treatment. Off-label uses of any product for which we obtain approval may subject us to additional liability.

Regulatory Risks

The results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate is safe and effective in advanced clinical trials involving large numbers of patients, we will be unable to submit the necessary application to receive regulatory approval to commercialize the product candidate. We face risks that:

- the product candidate may not prove to be safe or effective;
- the product candidate's benefits may not outweigh its risks;
- the results from advanced clinical trials may not confirm the positive results from pre-clinical studies and early clinical trials;
- the FDA or comparable foreign regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than us; and
- the FDA or other regulatory agencies may require additional or expanded trials and data.

We are subject to extensive governmental regulation, including the requirement of FDA approval or clearance, before our product candidates may be marketed.

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected. The FDA has determined that our technology and product candidates constitute "medical devices", and are thus subject to review by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case applicable governmental review requirements could vary in some respects and be more lengthy and costly.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers and our contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval and clearance requirements, numerous other regulatory requirements apply, both before and after approval or clearance, to us, our products and product candidates, and our suppliers and contract manufacturers. These include requirements related to the following:

- testing;
- manufacturing;
- quality control;
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with the use of the products; and
- obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

We are also subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA will not indentify compliance issues that may disrupt production or distribution, or require substantial resources to correct.

The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

Patients may discontinue their participation in our clinical studies, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Clinical trials for our product candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged to be related to our product candidates under evaluation. If a large number of patients in a study discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of the product candidate.

In addition, the time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the following:

- the size of the patient population;
- the nature of the clinical protocol requirements;
- the availability of other treatments or marketed therapies (whether approved or experimental);
- our ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient eligibility criteria for the study.

We rely on third parties to conduct our dermaPACE clinical trial, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.

We have engaged a clinical research organization (CRO) and other third party vendors to assist in the conduct of our clinical trial for dermaPACE. There are numerous sources that are capable of providing these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our dermaPACE clinical trial, the commercial prospects for the product could be harmed and our ability to generate product revenue would be delayed or prevented. Any failure of our CRO and other third party vendors to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our product and obtain regulatory approval. Problems with the timeliness or quality of the work of our CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our clinical trial, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trial in an acceptable manner and at an acceptable cost.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

Regulatory approval of our product candidates may be withdrawn at any time.

After regulatory approval has been obtained for medical device products, the product and the manufacturer are subject to continual review, including the review of adverse experiences and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions, or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturing facilities we use to make any of our products will also be subject to periodic review and inspection by the FDA or other regulatory authorities, as applicable. The discovery of any new or previously unknown problems with the product or facility may result in restrictions on the product or facility, including withdrawal of the product from the market. We will continue to be subject to the FDA or other regulatory authority requirements, as applicable, governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our product candidates, even those that the FDA or other regulatory authority, as applicable, had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in the United States Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes on us, if any, may be.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

International sales of our products and any of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the United States will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging and labeling requirements, and import restrictions on medical devices. In addition, each country has its own tariff regulations, duties and tax requirements. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. Our ability to market our approved products could be substantially limited due to

delays in receipt of, or failure to receive, the necessary approvals or clearances.

Prior to marketing our products in any country outside the United States, we must obtain marketing approval in that country. Approval and other regulatory requirements vary by jurisdiction and differ from the United States' requirements. We may be required to perform additional pre-clinical or clinical studies even if FDA approval has been obtained.

If we fail to obtain an adequate level of reimbursement for our approved products by third party payers, there may be no commercially viable markets for our approved products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our approved products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our approved products in the international markets in which those approvals are sought.

We believe that, in the future, reimbursement for any of our products or product candidates may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our products currently under development and limit our ability to sell our products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our approved products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our approved products would be impaired and our future revenues, if any, would be adversely affected.

Healthcare policy changes may have a material adverse effect on us.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), which substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the biotechnology and medical device industries. The PPACA includes, among other things, the following measures:

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, beginning in 2013;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biological products that are demonstrated to be biosimilar or interchangeable with a licensed biological product.

Certain of these provisions are still being implemented, and could meaningfully change the way healthcare is delivered and financed, and could have a material adverse impact on numerous aspects of our business. In the future there may continue to be additional proposals relating to the reform of the United States healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products, and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations and financial condition.

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in markets where we do business. We could experience an adverse impact on our operating results due to increased pricing pressure in the

United States and in other markets. Governments, hospitals and other third party payors could reduce the amount of approved reimbursement for our products or deny coverage altogether. Reductions in reimbursement levels or coverage or other cost-containment measures could adversely affect our future operating results.

If we fail to comply with the United States Federal Anti-Kickback Statute and similar state laws, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other Federal healthcare program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the Federal Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by Federal healthcare programs, but instead apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in Federal healthcare programs.

All of our financial relationships with healthcare providers and others who provide products or services to Federal healthcare program beneficiaries are potentially governed by the Federal Anti-Kickback Statute and similar state laws. We believe our operations are in compliance with the Federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the Federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

Product quality or performance issues may be discovered through ongoing regulation by the FDA and by comparable international agencies, as well as through our internal standard quality process.

The medical device industry is subject to substantial regulation by the FDA and by comparable international agencies. In addition to requiring clearance or approval to market new or improved devices, we are subject to ongoing regulation as a device manufacturer. Governmental regulations cover many aspects of our operations, including quality systems, marketing and device reporting. As a result, we continually collect and analyze information about our product quality and product performance through field observations, customer feedback and other quality metrics. If we fail to comply with applicable regulations or if post market safety issues arise, we could be subject to enforcement sanctions, our promotional practices may be restricted, and our marketed products could be subject to recall or otherwise impacted. Each of these potential actions could result in a material adverse effect on our business, operating results and financial condition.

The use of hazardous materials in our operations may subject us to environmental claims or liability.

We conduct research and development and manufacturing operations in our facility. Our research and development process may, at times, involve the controlled use of hazardous materials and chemicals. We will conduct experiments that are common in the medical device industry, in which we may use small quantities of chemicals, including those that are corrosive, toxic and flammable. The risk of accidental injury or contamination from these materials cannot be eliminated. We do not maintain a separate insurance policy for these types of risks. In the event of an accident or environmental discharge or contamination, we may be held liable for any resulting damages, and any liability could exceed our resources. We are subject to Federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant.

Risks Related to Intellectual Property

The protection of our intellectual property is critical to our success and any failure on our part to adequately protect those rights could materially adversely affect our business.

Our commercial success depends to a significant degree on our ability to:

- obtain and/or maintain protection for our product candidates under the patent laws of the United States and other countries;
- defend and enforce our patents once obtained;
- obtain and/or maintain appropriate licenses to patents, patent applications or other proprietary rights held by others with respect to our technology, both in the United States and other countries;
- maintain trade secrets and other intellectual property rights relating to our product candidates; and
- operate without infringing upon the patents, trademarks, copyrights and proprietary rights of third parties.

The degree of intellectual property protection for our technology is uncertain, and only limited intellectual property protection may be available for our product candidates, which may prevent us from gaining or keeping any competitive advantage against our competitors. Although we believe the patents that we own or license, and the patent applications that we own or license, generally provide us a competitive advantage, the patent positions of biotechnology, biopharmaceutical and medical device companies are generally highly uncertain, involve complex legal and factual questions and have been the subject of much litigation. Neither the United States Patent & Trademark Office nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Further, a court or other government agency could interpret our patents in a way such that the patents do not adequately cover our current or future product candidates. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon trade secrets and unpatented proprietary know-how and continuing technological innovation in developing our products, especially where we do not believe patent protection is appropriate or obtainable. We seek to protect this intellectual property, in part, by generally requiring our employees, consultants, and current and prospective business partners to enter into confidentiality agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants, researchers and advisors who we expect to work on our products and product candidates to agree to disclose and assign to us all inventions conceived during the work day, developed using our property or which relate to our business. We may lack the financial or other resources to successfully monitor and detect, or to enforce our rights in respect of, infringement of our rights or breaches of these confidentiality agreements. In the case of any such undetected or unchallenged infringements or breaches, these confidentiality agreements may not provide us with meaningful protection of our trade secrets and unpatented proprietary know-how or adequate remedies. In addition, others may independently develop technology that is similar or equivalent to our trade secrets or know-how. If any of our trade secrets, unpatented know-how or other confidential or proprietary information is divulged to third parties, including our competitors, our competitive position in the marketplace could be harmed and our ability to sell our products successfully could be severely compromised. Enforcing a claim that a party illegally obtained and is using trade secrets that have been licensed to us or that we own is also difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could have a material adverse effect on our business. Moreover, some of our academic institution licensees, evaluators, collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to protect our proprietary information or obtain patent protection in the future may be impaired, which could have a material adverse effect on our business.

In particular, we cannot assure you that:

- we or the owners or other inventors of the patents that we own or that have been licensed to us, or that may be issued or licensed to us in the future, were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;

any of our patent applications will result in issued patents;
the patents and the patent applications that we own or that have been licensed to us, or that may be issued or licensed to us in the future, will provide a basis for commercially viable products or will provide us with any competitive advantages, or will not be challenged by third parties;

- the patents and the patent applications that have been licensed to us are valid and enforceable;
- we will develop additional proprietary technologies that are patentable;
- we will be successful in enforcing the patents that we own or license and any patents that may be issued or licensed to us in the future against third parties;
- the patents of third parties will not have an adverse effect on our ability to do business; or
- our trade secrets and proprietary rights will remain confidential.

Accordingly, we may fail to secure meaningful patent protection relating to any of our existing or future product candidates or discoveries despite the expenditure of considerable resources. Further, there may be widespread patent infringement in countries in which we may seek patent protection, including countries in Europe and Asia, which may instigate expensive and time consuming litigation which could adversely affect the scope of our patent protection. In addition, others may attempt to commercialize products similar to our product candidates in countries where we do not have adequate patent protection. Failure to obtain adequate patent protection for our product candidates, or the failure by particular countries to enforce patent laws or allow prosecution for alleged patent infringement, may impair our ability to be competitive. The availability of infringing products in markets where we have patent protection, or the availability of competing products in markets where we do not have adequate patent protection, could erode the market for our product candidates, negatively impact the prices we can charge for our product candidates, and harm our reputation if infringing or competing products are manufactured to inferior standards.

Patent applications owned by or licensed to us may not result in issued patents, and our competitors may commercialize the discoveries we attempt to patent.

The patent applications that we own and that have been licensed to us, and any future patent applications that we may own or that may be licensed to us, may not result in the issuance of any patents. The standards that the United States Patent & Trademark Office and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to the type and scope of patent claims to which we may in the future be entitled under our license agreements or that may be issued to us in the future. These applications may not be sufficient to meet the statutory requirements for patentability and, therefore, may not result in enforceable patents covering the product candidates we want to commercialize. Further, patent applications in the United States that are not filed in other countries may not be published or generally are not published until at least 18 months after they are first filed, and patent applications in certain foreign countries generally are not published until many months after they are filed. Scientific and patent publication often occurs long after the date of the scientific developments disclosed in those publications. As a result, we cannot be certain that we will be the first creator of inventions covered by our patents or applications, or the first to file such patent applications. As a result, our issued patents and our patent applications could become subject to challenge by third parties that created such inventions or filed patent applications before us or our licensors, resulting in, among other things, interference proceedings in the United States Patent & Trademark Office to determine priority of discovery or invention. Interference proceedings, if resolved adversely to us, could result in the loss of or significant limitations on patent protection for our products or technologies. Even in the absence of interference proceedings, patent applications now pending or in the future filed by third parties may prevail over the patent applications that have been or may be owned by or licensed to us or that we may file in the future, or may result in patents that issue alongside patents issued to us or our licensors or that may be issued or licensed to us in the future, leading to uncertainty over the scope of the patents owned by or licensed to us or that may in the future be owned by us or our freedom to practice the claimed inventions.

Our patents may not be valid or enforceable, and may be challenged by third parties.

We cannot assure you that the patents that have been issued or licensed to us would be held valid by a court or administrative body or that we would be able to successfully enforce our patents against infringers, including our competitors. The issuance of a patent is not conclusive as to its validity or enforceability, and the validity and enforceability of a patent is susceptible to challenge on numerous legal grounds, including the possibility of reexamination proceedings brought by third parties in the United States Patent & Trademark Office against issued patents and similar validity challenges under foreign patent laws. Challenges raised in patent infringement litigation brought by or against us may result in determinations that patents that have been issued or licensed to us or any patents that may be issued to us or our licensors in the future are invalid, unenforceable or otherwise subject to limitations. In the event of any such determinations, third parties may be able to use the discoveries or technologies claimed in these patents without paying licensing fees or royalties to us, which could significantly diminish the value of our intellectual property and our competitive advantage. Even if our patents are held to be enforceable, others may be able to design around our patents or develop products similar to our products that are not within the scope of any of our patents.

In addition, enforcing the patents that we own or license and any patents that may be issued to us in the future against third parties may require significant expenditures regardless of the outcome of such efforts. Our inability to enforce our patents against infringers and competitors may impair our ability to be competitive and could have a material adverse effect on our business.

Issued patents and patent licenses may not provide us with any competitive advantage or provide meaningful protection against competitors.

The discoveries or technologies covered by issued patents we own or license may not have any value or provide us with a competitive advantage, and many of these discoveries or technologies may not be applicable to our product candidates at all. We have devoted limited resources to identifying competing technologies that may have a competitive advantage relative to ours, especially those competing technologies that are not perceived as infringing on our intellectual property rights. In addition, the standards that courts use to interpret and enforce patent rights are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, we cannot be certain as to how much protection, if any, will be afforded by these patents with respect to our products if we, our licensees or our licensors attempt to enforce these patent rights and those rights are challenged in court.

The existence of third party patent applications and patents could significantly limit our ability to obtain meaningful patent protection. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from pursuing research, development or commercialization of product candidates or may be required to obtain licenses, if available, to these patents or to develop or obtain alternative technology. If another party controls patents or patent applications covering our product candidates, we may not be able to obtain the rights we need to

those patents or patent applications in order to commercialize our product candidates or we may be required to pay royalties, which could be substantial, to obtain licenses to use those patents or patent applications.

In addition, issued patents may not provide commercially meaningful protection against competitors. Other parties may seek and/or be able to duplicate, design around or independently develop products having effects similar or identical to our patented product candidates that are not within the scope of our patents.

Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the protection we have under patents issued outside of the United States. We do not have patent protection for our product candidates in a number of our target markets. The failure to obtain adequate patent protection for our product candidates in any country would impair our ability to be commercially competitive in that country.

The ability to market the products we develop is subject to the intellectual property rights of third parties.

The biotechnology, biopharmaceutical and medical device industries are characterized by a large number of patents and patent filings and frequent litigation based on allegations of patent infringement. Competitors may have filed patent applications or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Third parties may claim that our products or related technologies infringe their patents. Further, we, our licensees or our licensors, may need to participate in interference, opposition, protest, reexamination or other potentially adverse proceedings in the United States Patent & Trademark Office or in similar agencies of foreign governments with regards to our patents, patent applications, and intellectual property rights. In addition, we, our licensees or our licensors may need to initiate suits to protect our intellectual property rights.

Litigation or any other proceeding relating to intellectual property rights, even if resolved in our favor, may cause us to incur significant expenses, divert the attention of our management and key personnel from other business concerns and, in certain cases, result in substantial additional expenses to license technologies from third parties. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An unfavorable outcome in any patent infringement suit or other adverse intellectual property proceeding could require us to pay substantial damages, including possible treble damages and attorneys' fees, cease using our technology or developing or marketing our products, or require us to seek licenses, if available, of the disputed rights from other parties and potentially make significant payments to those parties. There is no guarantee that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms. Even if we are able to obtain rights to a third party's patented intellectual property, those rights may be nonexclusive and, therefore, our competitors may obtain access to the same intellectual property. Ultimately, we may be unable to commercialize our product candidates or may have to cease some of our business operations as a result of patent infringement claims, which could materially harm our business. We cannot guarantee that our products or technologies will not conflict with the intellectual property rights of others.

If we need to redesign our products to avoid third party patents, we may suffer significant regulatory delays associated with conducting additional studies or submitting technical, clinical, manufacturing or other information related to any redesigned product and, ultimately, in obtaining regulatory approval. Further, any such redesigns may result in less effective and/or less commercially desirable products, if the redesigns are possible at all.

Additionally, any involvement in litigation in which we, our licensees or our licensors are accused of infringement may result in negative publicity about us or our products, injure our relations with any then-current or prospective customers and marketing partners, and cause delays in the commercialization of our products.

Risks Related to our Common Stock

Our stock price is volatile.

The market price of our Common Stock is volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- our ability to obtain additional financing and, if available, the terms and conditions of the financing;
- changes in the timing of clinical trial enrollment, the results of our clinical trials and regulatory approvals for our product candidates or failure to obtain such regulatory approvals;
- changes in our industry;
- additions or departures of key personnel;

- sales of our Common Stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- period-to-period fluctuations in our operating results;
- new regulatory requirements and changes in the existing regulatory environment; and
- general economic conditions and other external factors.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our Common Stock.

There is currently a limited trading market for our Common Stock and we cannot predict how liquid the market might become.

To date, there has been a limited trading market for our Common Stock and we cannot predict how liquid the market for our common stock might become. Our Common Stock is quoted on the Over-the-Counter Bulletin Board (OTCBB), which is an inter-dealer, over-the-counter market that provides significantly less liquidity than the New York Stock Exchange or the NASDAQ Stock Market. The quotation of our Common Stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market exists. The market price for our Common Stock is subject to volatility and holders of our common stock may be unable to resell their shares at or near their original purchase price, or at any price. In the absence of an active trading market:

- investors may have difficulty buying and selling, or obtaining market quotations for our Common Stock;
- market visibility for our Common Stock may be limited; and
- a lack of visibility for our Common Stock may have a depressive effect on the market for our common stock.

Trading for our Common Stock is limited under the SEC's penny stock regulations, which has an adverse effect on the liquidity of our common stock.

The trading price of our Common Stock is less than $5.00 per share and, as a result, our Common Stock is considered a "penny stock," and trading in our common stock is subject to the requirements of Rule 15g-9 under the Securities Exchange Act of 1934, as amended (Exchange Act). Under this rule, broker-dealers who recommend low-priced securities to persons other than established customers and accredited investors must satisfy special sales practice requirements. Generally, the broker-dealer must make an individualized written suitability determination for the purchaser and receive the purchaser's written consent prior to the transaction.

Regulations of the Securities and Exchange Commission (the "*SEC*") also require additional disclosure in connection with any trades involving a "penny stock," including the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and its associated risks. These requirements severely limit the liquidity of securities in the secondary market because only a few brokers or dealers are likely to undertake these compliance activities. Compliance with these requirements may make it more difficult for holders of our Common Stock to resell their shares to third parties or to otherwise dispose of them in the market.

As an issuer of "penny stock", the protection provided by the federal securities laws relating to forward looking statements does not apply to us.

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our Common Stock.

We have never paid cash dividends on our Common Stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our Common Stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

The rights of the holders of our Common Stock may be impaired by the potential rights of future holders (if any) of the Company's preferred stock.

Our board of directors has the right, without stockholder approval, to issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the voting power and equity interest of the holders of Common Stock, which could be issued with the right to more than one vote per share, and could be utilized as a method of discouraging, delaying or preventing a change of control. The possible negative impact on takeover attempts could adversely affect the price of our Common Stock.

Although we have no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

We have never held an annual meeting for the election of directors.

Pursuant to the provisions of the Nevada Revised Statutes (the "NRS"), directors are to be elected at the annual meeting of the stockholders. Pursuant to the NRS and our bylaws, our board of directors is granted the authority to fix the date, time and place for annual stockholder meetings. No date, time or place has yet been fixed by our board for the holding of an annual stockholder meeting. Pursuant to the NRS and our bylaws, each of our directors holds office after the expiration of his term until a successor is elected and qualified, or until the director resigns or is removed. Under the provisions of the NRS, if an election of our directors has not been made by our stockholders within 18 months of the last such election, then an application may be made to the Nevada district court by stockholders holding a minimum of 15% of our outstanding stockholder voting power for an order for the election of directors in the manner provided in the NRS.

We have not sought an advisory stockholder vote to approve the compensation of our named executive officers.

Rule 14a-21 under the Exchange Act requires us to seek a separate stockholder advisory vote at our annual meeting at which directors are elected to approve the compensation of our named executive officers, not less frequently than once every three years (say-on-pay vote), and, at least once every six years, to seek a separate stockholder advisory vote on the frequency with which we will submit advisory say-on-pay votes to our stockholders (say-on-frequency vote). In 2013, the year in which Rule 14a-21 became applicable to smaller reporting companies, we did not submit to our stockholders a say-on-pay vote to approve an advisory resolution regarding our compensation program for our named executive officers, or a say-on-frequency vote. Consequently, the board of directors has not considered the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers.

If the Company only raises the Minimum Offering Amount, we may not have sufficient capital to execute our business strategy.

If we close on the Minimum Offering, we may not have sufficient capital to execute on our business strategy the way we have intended. Our ability to obtain additional financing thereafter may have a materially adverse effect on our ability to execute its overall plan and your investment may be lost.

Investor funds will not accrue interest while in escrow prior to closing.

All funds delivered by investors in the United States in connection with subscriptions for the Common Stock and Warrants will be held in a non-interest bearing escrow account with the Escrow Agent until the closing of the offering, if any. If we are unable to sell and receive payments for the Minimum Offering Amount prior to March 31, 2016, investor subscriptions will be returned without interest or deduction. Investors in the Units offered hereby may not have the use of such funds or receive interest thereon pending the completion of the offering.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled ‘‘Prospectus Summary,’’ ‘‘Risk Factors,’’ ‘‘Management’s Discussion and Analysis of Financial Condition and Results of Operations’’ and ‘‘Business,’’ contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933. Statements in this prospectus that are not historical facts are hereby identified as ‘‘forward-looking statements’’ for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended (the “Securities Act”). Forward-looking statements convey our current expectations or forecasts of future events. All statements in this prospectus, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company’s future financial results, operating results, business strategies, projected costs, products, competitive positions, management’s plans and objectives for future operations, and industry trends. These forward-looking statements are based on management’s estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” and “co negative of these terms, or other comparable terminology. These forward-looking statements include, among other things, statements about:

- market acceptance of and demand for dermaPACE and our product candidates;
- regulatory actions that could adversely affect the price of or demand for our approved products;
- our intellectual property portfolio;
- timing of clinical studies and eventual FDA approval of our products;
- our marketing and manufacturing capacity and strategy;
- estimates regarding our capital requirements, and anticipated timing of the need for additional funds;
- product liability claims;
- economic conditions that could adversely affect the level of demand for our products;
- financial markets; and
- the competitive environment.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in the section titled ‘‘Risk Factors.’’ In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should read this prospectus and the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of Units by us, assuming the sale of all of the Units will be approximately $3,580,000 in the case of the Maximum Offering, and $1,330,000 in the case of the Minimum Offering, after deducting estimated offering expenses payable by us, based upon an assumed public offering price of $0.06 per Unit.

We intend to use the net proceeds from the sale of Units by us to pay down the HealthTronics debt as required by the amendment in the amount of 20% of the net proceeds of the offering and for expenses related to the 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.

Until we use the net proceeds of this offering, we may invest the net proceeds in short-term, investment-grade securities. We cannot predict whether the proceeds invested will yield a favorable return.

This prospectus also relates to shares of our Common Stock that may be offered and sold from time to time by the selling stockholders who will receive all of the proceeds from the sale of the shares. We will not receive any proceeds from the sale of shares of Common Stock by selling stockholders in this offering.

We will bear all expenses of registration incurred in connection with this offering, but all commissions, selling and other expenses incurred by the selling stockholders to underwriters, agents, brokers and dealers will be borne by them. We estimate that our expenses in connection with the filing of the registration statement of which this prospectus is a part will be approximately $45,000.

SELLING STOCKHOLDERS

This prospectus relates to the possible resale of up to 23,545,114 shares of our Common Stock that were issued and outstanding as of the date of the effectiveness of the registration statement of which this prospectus forms a part.

Selling Stockholder Table

The table set forth below lists the selling stockholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder) of the shares of Common Stock held by each of the selling stockholders.

The selling stockholders identified in this prospectus may offer the shares of our common stock at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale or at negotiated prices. See “Plan of Distribution” for additional information.

Unless otherwise indicated, we believe, based on information supplied by the following persons, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own. The registration of the offered shares does not mean that any or all of the selling stockholders will offer or sell any of the shares of common stock upon any such exchange.

	Number of Shares beneficially owned prior to this offering [1]			Number of Shares being offered			Number of Shares beneficially owned after this offering [11]	
Name of Beneficial Owner	**Number**		**Percent**	**Number**		**Percent**	**Number**	**Percent**
Directors and Executive Officers:								
Kevin A. Richardson, II [2]	8,902,588		12.6%	406,244		0.6%	8,496,344	7.5%
John F. Nemelka [3]	382,248		0.6%	46		*	382,202	0.3%
Alan Rubino [4]	350,000		0.5%	-		-		
All directors and executive officers as a group (3 persons)	9,634,836		13.7%	-		-		
Principal and/or Selling Shareholders:								
RA Capital Healthcare Fund, L.P. [5]	9,956,624		14.1%	9,956,624		14.1%	-	-
Prides Capital Fund I, LP [6]	5,514,081		7.8%	4,851,719		6.9%	5,514,081	4.9%
Tudor BVI Global Portfolio Ltd. [7]	1,494,552		2.1%	1,494,552		2.1%	-	-
A. Michael Stolarski [8] [9]		1,233,444	1.7%		1,233,444	1.7%	-	-
NightWatch Capital Partners, LP [10]	1,020,446		1.4%	1,020,446		1.4%	-	-
The Trustees of Columbia University in City of New York [7]	656,074		0.9%	656,074		0.9%	-	-
NightWatch Capital Partners (Cayman) Ltd. [10]	454,101		0.6%	454,101		0.6%	-	-
Crown Investment Fund [7]	238,585		0.3%	238,585		0.3%	-	-
MAZ Partners LP [9]		201,085	0.3%		201,085	0.3%	-	-
AMA U.S. Equity Opportunity Fund (QP) LP [10]	182,296		0.3%	182,296		0.3%	-	-
Brenda Hall [8]		163,991	0.2%		163,991	0.2%	-	-
Hallador Alternative Assets Fund,LLC [7]	158,649		0.2%	158,649		0.2%	-	-
Palladian Partners IV, LLC [7]	152,244		0.2%	152,244		0.2%	-	-
Oppenheimer & Co., Inc. [8]		149,349	0.2%		149,349	0.2%	-	-
HealthTronics, Inc. [7]	138,782		0.2%	138,782		0.2%	-	-
Michael S. Barish [8]		129,867	0.2%		129,867	0.2%	-	-
Frederick Wahl [8]		117,137	0.2%		117,137	0.2%	-	-
John S. Irish [8]		117,137	0.2%		117,137	0.2%	-	-

Dassity, Inc. [8]		106,209	0.2%		106,209	0.2%	-	-
Palladian Partners V, LLC [7]	88,756		0.1%	88,756		0.1%	-	-
Fred Bohlander [8]		88,618	0.1%		88,618	0.1%	-	-
Sharon Borg Wall [8]		88,286	0.1%		88,286	0.1%	-	-
Echelon Partners LP [7]	82,055		0.1%	82,055		0.1%	-	-
El Coronado Holdings, LLC [7]	71,517		0.1%	71,517		0.1%	-	-
Thunder Basin Corporation [10]	65,800		0.1%	65,800		0.1%	-	-
Taylor Waypoint Fund, LP [10]	61,359		0.1%	61,359		0.1%	-	-
Nortrust Nominees Ltd Leperq Amcur Sicav FIS [7]	61,020		0.1%	61,020		0.1%	-	-
John M. Fay [8]		59,666	0.1%		59,666	0.1%	-	-
Palladian Partners V-A, LLC [7]	59,170		0.1%	59,170		0.1%	-	-
Hallador Balance Fund LLC [7]	58,019		0.1%	58,019		0.1%	-	-
Lime Partners, LLC [7]	49,380		0.1%	49,380		0.1%	-	-
Belfer Investment Partners, LP [7]	49,380		0.1%	49,380		0.1%	-	-
Robert A. Belfer Descendants' Trust [7]	49,380		0.1%	49,380		0.1%	-	-
Stacy Family Trust [10]	47,710		0.1%	47,710		0.1%	-	-
Nortrust Nominees A/C Leperq-Lynx Partner [7]	44,700		0.1%	44,700		0.1%	-	-
The Indick/Lachman Revocable Trust [7]	44,262		0.1%	44,262		0.1%	-	-
Nightwatch Capital Management, LLC [7]	40,025		0.1%	40,025		0.1%	-	-
Lynx Managed Equity Master Fund, LP [7]	36,833		0.1%	36,833		0.1%	-	-
P. Paul and Assocaites [7]	31,495		*	31,495		*	-	-
Taylor Insurance Series LP - Series G [7]	30,916		*	30,916		*	-	-
Carlson Capital, LP [7]	29,712		*	29,712		*	-	-
Charlie McCarthy [7]	27,081		*	27,081		*	-	-
Booth and Company, Nominee A/C Lepercq Partners Fund, L.P. [7]	25,984		*	25,984		*	-	-
Peter T. Paul Living Trust [7]	25,792		*	25,792		*	-	-
KMS Opportunity Fund [7]	25,212		*	25,212		*	-	-
Renee Holdings Partnership, LP [7]	24,689		*	24,689		*	-	-
2006 Paul Partnership, LP [7]	24,445		*	24,445		*	-	-
Elizabeth Rice Grossman Family Trust [7]	23,839		*	23,839		*	-	-

Elizabeth Grossman IRA [7]	23,802		*	23,802	*	-	-
Hank Lawlor [7]	16,658		*	16,658	*	-	-
Nadel & Gussman Combined Funds, LLC [10]	16,141		*	16,141	*	-	-
Berkowitz Trust U/A/D 9/01/95 [7]	15,470		*	15,470	*	-	-
Taylor Investments Class F [7]	14,924		*	14,924	*	-	-
Christian Puscasiu [7]	12,108		*	12,108	*	-	-
Murray Indick, IRA / RO [7]	11,306		*	11,306	*	-	-
Michael Weinberg [7]	9,760		*	9,760	*	-	-
George Johnson [8]		7,450	*		7,450	*	-	-
Nicholas A Halaby [7]	5,954		*	5,954	*	-	-
Rob Santangelo, IRA [7]	5,954		*	5,954	*	-	-
Jeff and Janice Mondry [7]	5,554		*	5,554	*	-	-
Stephen E. Cootey [7]	5,244		*	5,244	*	-	-
Lawrence Becerra [10]	5,014		*	5,014	*	-	-
KCS [7]	4,986		*	4,986	*	-	-
Roy Trice [7]	4,814		*	4,814	*	-	-
Demar-Collins Children's Trust [10]	4,712		*	4,712	*	-	-
Robert J. Leerink [7]	4,061		*	4,061	*	-	-
Intellivestor, LLC [7]	3,519		*	3,519	*	-	-
Christian Puscasiu Roth [7]	3,096		*	3,096	*	-	-
Charlie McCarthy, IRA [7]	3,011		*	3,011	*	-	-
Paul Harris [10]	2,761		*	2,761	*	-	-
Stuart Harris [10]	2,761		*	2,761	*	-	-
Brad and Kelly Eichler [7]	2,391		*	2,391	*	-	-
Charles Jobson [7]	2,382		*	2,382	*	-	-
Michael McCarthy [7]	2,368		*	2,368	*	-	-
Peter Zecca, Jr. [7]	2,353		*	2,353	*	-	-
Christopher Wynne [8]		1,335	*		1,335	*	-	-
Ameriprise Financial, FBO Paul V. Burgon IRA [10]	744		*	744	*	-	-
Youghiogheny Holdings [7]	518		*	518	*	-	-
Paul Burgon [10]	229		*	229	*	-	-
Asagard investment Corporation [7]	52		*	52	*	-	-

(1) Applicable percentage ownership is based on 70,504,473 shares of common stock outstanding as of January 15, 2016, “Beneficial ownership” includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of January 15, 2016. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.

(2) Includes options to purchase up to 865,000 shares of common stock and warrants to purchase up to 218,947 shares of common stock. In addition, this amount includes 5,805,371 shares of common stock and warrants to purchase 662,362 shares of common stock owned directly by Prides Capital Fund I, L.P. Prides Capital Partners LLC is the general partner of Prides Capital Fund I, L.P. and Mr. Richardson is the controlling shareholder of Prides Capital Partners LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. Richardson has also been deputized by Prides Capital Partners LLC to serve on the board of directors of the Company. Mr. Richardson disclaims beneficial ownership of all such securities except to the extent of any indirect pecuniary interest (within the meaning of Rule 16a-1 of the Exchange Act) therein.

(3) Includes options to purchase up to 365,000 shares of common stock. In addition, this amount includes warrants to purchase 16,702 shares of common stock owned directly by NightWatch Capital Partners II, L.P. NightWatch Capital Management, LLC, is the general partner of NightWatch Capital Partners II, L.P. and Mr. John Nemelka is the controlling shareholder of NightWatch Capital Management LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. John Nemelka has also been deputized by NightWatch Capital Management LLC to serve on the board of directors of the Company. Mr. John Nemelka disclaims beneficial ownership of all such securities except to the extent of any indirect pecuniary interest (within the meaning of Rule 16a-1 of the Exchange Act) therein.

(4) Consists of options to purchase up to 350,000 shares of common stock.

(5) Shares reported herein for RA Capital Healthcare Fund, L.P. represent 5,291,451 shares of common stock issued upon the conversion of Series A Warrants held of record by the fund. Shares reported herein for RA Capital Management, LLC represent (a) the above-referenced shares of common stock issuable upon the conversion of certain warrants as reported for RA Capital Healthcare Fund, L.P. for which RA Capital Management, LLC serves as the sole general partner, (b) 3,072,114 shares of common stock equivalents from Series B Convertible Preferred Stock, (c) 1,007,895 shares of shares of common stock issued upon the conversion of Series A Warrants and (d) 585,164 shares of common stock equivalents from Series B Convertible Preferred Stock held in a separately managed account for Blackwell Partners, LLC for which RA Capital Management, LLC serves as investment adviser. Each of the Reporting Persons disclaims beneficial ownership of the shares reported herein except to the extent of its or his pecuniary interest therein. The principal business office of the Reporting Persons is c/o RA Capital Management, LLC, 20 Park Plaza, Suite 1200, Boston, MA 02116.

(6) Based solely on information contained in filings on Schedule 13D, as amended, made with the SEC by the reporting person and on records of the Company. Includes warrants to purchase 662,362 shares of common stock. The principal business address of Prides Capital Fund, I, LP is 100 Cummings Center, Suite 324C, Beverly, MA 01915. Kevin A. Richardson, II, has voting and dispositive power over the securities. See footnote (2).

(7) Based on the distribution of shares of Prides Captial Fund I, L.P. in September 2015.

(8) Shares issued in conversion of Series A Warrants into Common Stock on January 14, 2016.

(9) Based on records of the Company.

(10) Based on the distribution of shares of NightWatch Capital Partners II, L.P.

(11) Assumes the sale of all of the shares offered by the selling stockholders under this prospectus and 120,504,473 shares of Common Stock outstanding after this offering, giving pro forma effect to the case of the Maximum Offering.

PLAN OF DISTRIBUTION

Distribution

Newport Coast Securities, Inc. which we refer to herein as the Placement Agent, has agreed to act as a placement agent in connection with this offering subject to the terms and conditions of the placement agent agreement dated December 11, 2015. The Placement Agent is not purchasing or selling any securities offered by this prospectus, nor is it required to arrange the purchase or sale of any specific number or dollar amount of securities, but has agreed to use their best efforts to arrange for the sale of all or none of at least the Minimum Offering of Units offered hereby. Therefore, we will enter into a subscription agreement directly with investors in connection with this offering and we may not sell the entire amount of securities offered pursuant to this prospectus. The Placement Agent may retain other brokers or dealers to act as sub-agents or selected-dealers on its behalf in connection with the offering.

We have agreed to pay the Placement Agent a 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, 25,000,000 Units, the Placement Agent will be issued warrants to purchase 2,500,000 shares of Common Stock at an exercise price of $0.08 per share and in the case of the Maximum Offering, 66,666,667 Units, the Placement Agent will be issued warrants to purchase 6,666,667 shares of Common Stock at an exercise price of $0.08 per share.

As required by FINRA pursuant to Rule 5110(g)(1), neither the Placement Agent’s Warrants nor any shares of common stock issued upon exercise of the Placement Agent’s Warrants may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date hereof, except the transfer of any security:

- by operation of law or by reason of our reorganization;
- to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period;
- if the aggregate amount of our securities held by the placement agent or related person do not exceed 1% of the securities being offered;
-

that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or

- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

Escrow Arrangements

Placement Agent and the Company shall instruct investors to deliver to Escrow Agent checks made payable to the order of "Signature Bank, as Escrow Agent for SANUWAVE Health, Inc.," or wire transfer to Signature Bank, 261 Madison Avenue, New York, New York 10016, ABA No. 026013576 for credit to Signature Bank, as Escrow Agent for SANUWAVE Health, Inc., Account No. 1502623709, in each case, with the name and address of the individual or entity making payment. In the event that any Investor's address is not provided to Escrow Agent by the Investor, then Placement Agent and/or Company agree to promptly provide Escrow Agent with such information in writing. The check or wire transfers shall be deposited into a non interest-bearing account at Signature Bank entitled SANUWAVE Health, Inc., Signature Bank, as Escrow Agent (the "Escrow Agent"). No investor funds will be accepted prior to effectiveness of the Registration Statement. After the Registration Statement is declared effective and prior to the closing date, all investor funds will be placed promptly, and in any event no later than noon Eastern Standard Time of the next business day following receipt, in escrow with the Escrow Agent in an escrow account established for the benefit of the investors. Prior to the closing date, the Escrow Agent will advise the Company whether the investors have deposited the requisite funds in the escrow account with the Escrow Agent. If the requisite funds have been deposited, the Company's transfer agent will deposit with The Depository Trust Company the securities to be credited to the respective accounts of the investors. Investor funds will be collected by the Company through the facilities of the Escrow Agent on the scheduled closing date. In the event that requisite investor funds are not received by the closing date, all funds deposited in the escrow account will promptly be returned in full.

Because there cannot be any assurance that Maximum Offering Amount will be sold in this offering, the actual total offering commissions, if any, are not presently determinable.

If we do not sell and receive payments for the Minimum Offering Amount prior to March 31, 2016, investor subscriptions will be returned without interest or deduction.

Our obligations to issue and sell the Units to the purchasers is subject to the conditions set forth in the subscription agreement, which may be waived by us at our discretion. A purchaser's obligation to purchase the shares of common stock and warrants is subject to the conditions set forth in the subscription agreement as well, which may also be waived.

We estimate the total offering expenses in this offering that will be payable by us, excluding the Placement Agent' fees, will be approximately $45,000 which include legal, accounting and printing costs, various other fees and reimbursement of the Placement Agent' expenses. Such fees and expense reimbursement to the Placement Agent total approximately $24,000 and are payable in addition to the commission-based compensation disclosed in the second paragraph of this Plan of Distribution.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agent agreement and the subscription agreement. A copy of the placement agent agreement and the form of subscription agreement with investors are included as exhibits to the Registration Statement of which this prospectus forms a part.

The Placement Agent may be deemed to be underwriters within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by them and any profit realized on the resale of the securities underlying the Units sold by them while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As underwriters, the Placement Agent would be required to comply with the Securities Act and the Securities Exchange Act of 1934, as amended, including without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent acting as principal.

Under these rules and regulations, the Placement Agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Lock-Up Agreements

Pursuant to certain "lock-up" agreements, (a) our executive officers and directors as of the pricing date of the offering, will agree, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any securities of the company without the prior written consent of the Placement Agent, for a period of 90 days from the date of the final prospectus of the offering, and (b) we, and any successor, will agree, subject to certain exceptions, not to for a period of 90 days from the date of the final prospectus of the offering (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our capital stock; (2) file or caused to be filed any registration statement with the SEC relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our capital stock, whether any such transaction described in (1), (2), or (3) above is to be settled by delivery of shares of our capital stock or such other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit, among other things, (1) the issuance by us of stock options pursuant to our existing stock incentive plans, or (2) the issuance of common stock upon the exercise of outstanding stock options and warrants.

Our Participation

Rule 3a4-1 sets forth those conditions under which a person associated with an issuer may participate in the offering of the issuer's securities and not be deemed to be a broker-dealer. Those conditions are as follows:

a. Our officers and directors are not subject to a statutory disqualification, as that term is defined in Section 3(a)(39) of the Act, at the time of their participation;

b. Our officers and directors will not be compensated in connection with their participation by the payment of commissions or other remuneration based either directly or indirectly on transactions in securities;

c. Our officers and directors are not, nor will they be at the time of their participationin the offering, an associated person of a broker-dealer; and

d. Our officers and directors meet the conditions of paragraph (a)(4)(ii) of Rule 3a4-1 of the Exchange Act, in that they (A) primarily perform, or intend primarily to perform at the end of the offering, substantial duties for or on behalf of our Company, other than in connection with transactions in securities; and (B) are not a broker or dealer, or been associated person of a broker or dealer, within the preceding twelve months; and (C) have not participated in selling and offering securities for any Issuer more than once every twelve months other than in reliance on Paragraphs (a)(4)(i) and (a)(4)(iii).

Certain of our affiliates may purchase Units in this offering on the same terms as they are offered and sold to the public.

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses will be approximately $45,000, all of which are payable by us.

Pricing of this Offering

The public offering price of the Units was determined by us. Factors considered in determining the prices and terms of the shares include:

- the history and prospects of companies in our industry;
- prior offerings of those companies;
- our prospects for developing and commercializing our products;
- our capital structure;
- an assessment of our management and their experience;
- general conditions of the securities markets at the time of the offering; and
- other factors as were deemed relevant.

Penny Stock

The SEC has adopted Rule 15g-9 which establishes the definition of a ”penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our Common Stock and cause a decline in the market value of our Common Stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock.

Offering by Selling Stockholders

We are registering the shares of Common Stock issued to the selling stockholders to permit the resale of these shares of Common Stock by the selling stockholders, from time to time, after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of Common Stock.

The selling stockholders may sell all or a portion of the shares of Common Stock held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of Common Stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales made after the date the Registration Statement is declared effective by the SEC;
- broker-dealers may agree with a selling security holder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares of Common Stock under Rule 144 promulgated under the Securities Act of 1933, as amended, if available, rather than under this prospectus. In addition, the selling stockholders may transfer the shares of Common Stock by other means not described in this prospectus. If the selling stockholders effect such transactions by selling shares of Common Stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any amendment to this

prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the selling stockholders and any broker-dealer participating in the distribution of the shares of Common Stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares of Common Stock in violation of any applicable securities laws. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of Common Stock to engage in market-making activities with respect to the shares of Common Stock. All of the foregoing may affect the marketability of the shares of Common Stock and the ability of any person or entity to engage in market-making activities with respect to the shares of Common Stock.

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

The Company’s Common Stock is quoted on the OTCBB under the symbol “SNWV”.

The following table sets forth, for the periods indicated, the high and low sales prices per share of our Common Stock, as reported on the OTCBB. The quotations reflect inter-dealer prices, without mark-up, mark-down or commissions, and may not represent actual transactions:

	Price Range	
	High	**Low**
2016		
First Quarter (through February 12, 2016)	$0.09	$0.06

	Price Range	
	High	**Low**
2015		
First Quarter	$0.28	$0.11
Second Quarter	$0.25	$0.04
Third Quarter	$0.19	$0.09
Fourth Quarter	$0.17	$0.06

	Price Range	
	High	**Low**
2014		
First Quarter	$0.81	$0.52
Second Quarter	$0.70	$0.44
Third Quarter	$0.53	$0.20
Fourth Quarter	$0.22	$0.04

	Price Range	
	High	**Low**
2013		
First Quarter	$0.95	$0.16
Second Quarter	$1.59	$0.60
Third Quarter	$0.90	$0.45
Fourth Quarter	$0.82	$0.64

See the cover page of this prospectus for a recent bid price of our Common Stock as reported by the OTC Bulletin Board.

As of February 12, 2016, there were 70,504,473 shares of our Common Stock outstanding and approximately 119 holders of record of our Common Stock. However, we believe that there are more beneficial holders of our Common Stock as many beneficial holders hold their stock in “street name.”

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	-	$ 0.00	-
Equity compensation plans not approved by security holders	8,573,385	$ 0.64	3,758,281
Total	8,573,385	$ 0.64	3,758,281

Stock Incentive Plans

During 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc., and certain non-statutory stock option agreements with key employees outside of the 2006 Stock Incentive Plan. The non-statutory stock option agreements have terms substantially the same as the 2006 Stock Incentive Plan. The stock options granted under the plans were nonstatutory options which vest over a period of up to four years, and have a ten year term. The options were granted at an exercise price equal to the fair market value of the common stock on the date of the grant, which was approved by the board of directors of the Company.

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "*Stock Incentive Plan*"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include nonstatutory options as well as qualified incentive stock options. The Stock Incentive Plan is currently administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are nonstatutory options which vest over a period of up to three years, and have a ten year term. The options are granted at an exercise price equal to the fair market value of the common stock on the date of the grant which is approved by the board of directors of the Company.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding our business development plans, clinical trials, regulatory reviews, timing, strategies, expectations, anticipated expenses levels, projected profits, business prospects and positioning with respect to market, demographic and pricing trends, business outlook, technology spending and various other matters (including contingent liabilities and obligations and changes in accounting policies, standards and interpretations) and express our current intentions, beliefs, expectations, strategies or predictions. These forward-looking statements are based on a number of assumptions and currently available information and are subject to a number of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections titled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" and elsewhere in this prospectus. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

Overview

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.

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.

Recent Developments

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 as of April 30, 2014, we had enrolled the minimum number of 90 patients in the clinical trial, which represented the number of patients for the first interim analysis by the independent Data Monitoring Committee (DMC). In September 2014, we reported that the independent Data Monitoring Committee had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the clinical trial and recommended we continue enrollment of patients into the study up to the next predefined patient analysis point of 130 patients. We completed enrollment for the 130 patients in November 2014 and suspended further enrollment at that time.

The DMC performed an analysis of the primary efficacy endpoint of the rate of 100% complete wound closure at the 12-week endpoint for the dermaPACE treated patients as compared to the sham-control patients and the safety data.

The DMC has completed its review and noted there were no safety issues. The DMC reported the Monitoring Success Criterion for primary efficacy endpoint of 100% complete wound closure at 12 weeks has not been met and, assuming similar trends for any additional patents enrolled, will likely not be met at the next predefined analysis point of 170 patients. The Monitoring Success Criterion is a predictive probability of dermaPACE achieving statistical significance in the rate of 100% complete wound closure at 12 weeks as compared to the rate for sham-control.

As per its charter, the DMC's review was limited to only the 12-week endpoint data. The DMC has requested to us the ability to review complete closure rates at later points in the study, as patients were followed for up to 24 weeks and the DMC noted we had positive results in the first study of 206 patients completed in 2011 at the 20-week endpoint.

We have retained Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in January 2015 to lead the Company's interactions and correspondence with the FDA for the dermaPACE, which have already commenced. MCRA has successfully worked with the FDA on numerous Premarket Approvals (PMAs) for various musculoskeletal, restorative and general surgical devices since 2006.

We, including our regulatory advisor MCRA, held an in-person meeting with the FDA in June 2015 and in this meeting, it was determined that the best path would be for us to retain the original analysis plan. In addition, the FDA noted the totality of the data from the clinical study, such as additional endpoints and a favorable risk/benefit profile, will play an important role in the FDA's review of our PMA submission.

All 130 of the patients enrolled as of November 2014 have completed the full 24-week follow-up at this time. We worked with our Clinical Research Organization (CRO), CPC Clinical Research, Inc., to complete the auditing of the clinical documentation at each clinical site, perform site close-out visits, complete a final review and then locked the clinical study database in August 2015. We have conducted preliminary statistical analyses and announced that we did not reach statistical significance at 12 weeks, however our clinical study did show efficacy at 20 weeks when combining the two trials. There were no serious or related adverse events associated with dermaPACE treatment reported during the course of the two studies and there were no issues regarding the tolerability of the treatment. Due to the safety profile of our device and the efficacy of the data at 20 weeks, we are moving forward with our PMA submission to the FDA and expect to make our submission in early first quarter of 2016. We will be working with MCRA in developing a submission strategy and to serve as the key element in communication with FDA during the pre and post PMA submission process.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the pivotal trial (discussed below). Similar to the pivotal trial, four (4) dermaPACE procedures are administered during the first two weeks following subject enrollment. In the current trial, however, up to four (4) additional dermaPACE procedures are delivered bi-weekly, between weeks 4 and 10 following subject enrollment, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical study. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted pivotal study. Bayesian designs are supported by the FDA where there is strong prior evidence that can be incorporated into the clinical study design. By incorporating the prior positive information regarding complete wound closure after one treatment cycle into the design of the current study, substantially fewer patients are required than would otherwise be the case while still ensuring adequate statistical power. This approach saves significant time and preserves scientific rigor.

Our dermaPACE device has received the European CE Mark approval to treat acute and chronic defects of the skin and subcutaneous soft tissue, such as in the treatment of pressure ulcers, diabetic foot ulcers, burns, and traumatic and surgical wounds. We are actively marketing dermaPACE to the European Community, Canada and Asia/Pacific, utilizing distributors in select countries.

Previous clinical work supporting our current dermaPACE clinical study

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 July 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. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

A total of 206 patients entered the dermaPACE study at 24 sites. The patients in the study were followed for a total of 24 weeks. The study's primary endpoint, wound closure, was defined as "successful" if the skin was 100% reepithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits.

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) sham-control subjects.
- In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of sham-control subjects (p=0.047); in the efficacy evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of sham-control subjects (p=0.018).
- Subjects treated with dermaPACE achieved a significant increase in the rate of complete and/or ≥90% wound closure. We analyzed a clinically relevant ≥ 90% wound closure endpoint that demonstrated statistical significance (p=0.0161) in favor of dermaPACE subjects (51/107, 48%) compared to patients randomized to receive sham-control (31/99, 31%).
- Within 6 weeks following the initial dermaPACE treatment, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control (p<0.05).
- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20.0% in the sham-control group.
- Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

We filed with the FDA the clinical module of the dermaPACE PMA application in June 2011. 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. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

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.

Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2015, we had cash and cash equivalents totaling $625,450. Management has obtained two 8% Convertible Promissory Notes totaling $100,000 to fund operations until the Minimum Offering amount is raised. Management expects the cash used in operations for the Company during the first two quarters of 2016 will be approximately $200,000 to $250,000 per month, exclusive of FDA submission costs, as resources are devoted to the review and analysis of the clinical data results phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers and preparation of the submission strategy to the FDA. We will not know the costs for our FDA submission until after our submission strategy meeting with the FDA, expected to occur in late March or early April.

We do not currently generate significant recurring revenue and will require additional capital before the conclusion of the first quarter of 2016. We may raise 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 by selling all or a portion of the Company's assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions should provide the necessary funding for us.

Since our inception, we have incurred losses from operations each year. As of September 30, 2015, we had an accumulated deficit of $91,891,615. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next several years as we continue to fund the dermaPACE clinical trial and the FDA approval process.

We cannot reasonably estimate the nature, timing and costs of the efforts necessary to complete the development and approval of, or the period in which material net cash flows are expected to be generated from, any of our products, due to the numerous risks and uncertainties associated with developing products, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of successful marketing, sales and distribution;
- the cost and timing associated with establishing reimbursement for our products;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior.

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth under the section entitled "Risk Factors – Risks Related to Our Business".

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to the recording of the allowances for doubtful accounts, estimated reserves for inventory, estimated useful life of property and equipment, the determination of the valuation allowance for deferred taxes, the estimated fair value of stock-based compensation, and the estimated fair value of intangible assets. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements filed with this registration statement on Form S-1, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, intangible assets, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

Sales of medical devices, including related applicators and applicator kits, are recognized when shipped to the customer. Shipments under agreements with distributors are invoiced at a fixed price, are not subject to return, and payment for these shipments is not contingent on sales by the distributor. We recognize revenue on shipments to distributors in the same manner as with other customers. We recognize fees from services performed when the service is performed.

Research and Development Costs

We expense costs associated with research and development activities as incurred. We evaluate payments made to suppliers and other vendors and determine the appropriate accounting treatment based on the nature of the services provided, the contractual terms, and the timing of the obligation. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs.

Inventory Valuation

We value our inventory at the lower of our actual cost or the current estimated market value. We regularly review existing inventory quantities and expiration dates of existing inventory to evaluate a provision for excess, expired, obsolete and scrapped inventory based primarily on our historical usage and anticipated future usage. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated change in demand or technological developments could have an impact on the value of our inventory and our reported operating results.

Inventory is carried at the lower of cost or market, which is valued using the first in, first out (FIFO) method, and consists primarily of devices and the component material for assembly of finished products, less reserves for obsolescence.

Intangible Assets

Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over the average life of 11.4 years. We regularly review intangible assets to determine if facts and circumstances indicate that the useful life is shorter than we originally estimated or that the carrying amount of the assets may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the intangible assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If recognition of an impairment charge is necessary, it is measured as the amount by which the carrying amount of the intangible asset exceeds the fair value of the intangible asset.

Stock-based Compensation

The Stock Incentive Plan provides that stock options, and other equity interests or equity-based incentives, may be granted to key personnel, directors and advisors at the fair value of the common stock at the time the option is granted, which is approved by our board of directors. The maximum term of any option granted pursuant to the Stock Incentive Plan is ten years from the date of grant.

In accordance with ASC 718, *Compensation – Stock Compensation* (formerly SFAS No. 123(R), Accounting for Stock-Based Compensation), the fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The expected terms of options granted represent the period of time that options granted are estimated to be outstanding and are derived from the contractual terms of the options granted. We amortize the fair value of each option over each option’s vesting period.

Income Taxes

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109, Accounting for Income Taxes). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets, including loss carryforwards, when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We account for uncertain tax positions in accordance with the related provisions of ASC 740, *Income Taxes* (formerly FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48)). ASC 740 specifies the way public companies are to account for uncertainties in income tax reporting, and prescribes a methodology for recognizing, reversing, and measuring the tax benefits of a tax position taken, or expected to be taken, in a tax return. ASC 740 requires the evaluation of tax positions taken or expected to be taken in the course of preparing our tax returns to determine whether the tax positions would “more-likely-than-not” be sustained if challenged by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax benefit or expense in the current year.

Results of Operations for the Nine Months ended September 30, 2015 and 2014 (Unaudited)

Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2015 were $594,040, compared to $610,705 for the same period in 2014, a decrease of $16,665, or 3%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The decrease in revenues for 2015 was mainly due to the impact of the changes in foreign currently rates primarily for sales in Euros as there are higher sales of orthoPACE devices and applicators in 2015.

Cost of revenues for the nine months ended September 30, 2015 were $173,349, compared to $149,813 for the same period in 2014. Gross profit as a percentage of revenues was 71% for the nine months ended September 30, 2015, compared to 76% for the same period in 2014. The decrease in gross profit as a percentage of revenues in 2015 was due to the combination of one more device sale in 2015 as compared to 2014, and twenty-one less wound kits sold in 2015 as compared to 2014. Device sales have a low margin and wound kits have a high margin.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2015 were $1,660,546, as compared to $2,486,801 for the same period in 2014, a decrease of $826,255, or 33%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs. Research and development expenses decreased in 2015 as a result of lower headcount in the clinical department and lower payments to third party clinical sites participating in the dermaPACE clinical study as there were fewer active patients in the clinical study in 2015 as compared to 2014.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2015 were $1,981,541, as compared to $2,774,828 for the same period in 2014, a decrease of $793,287, or 29%. The decrease in general and administrative expenses is primarily due to reduced consulting expenses which are partially offset by higher legal fees related to employee matters and patent filings in 2015.

Other Expense

Other expense was $253,253 for the nine months ended September 30, 2015, as compared to $706,393 for the same period in 2014, a decrease in other expense of $453,140, or 64%. The decrease in other expense for 2015 was due to $460,118 in interest expense recorded in 2014 related to promissory notes repaid in full in March 2014 and gain on sale of property and equipment of $100,000 in 2015, which was offset by loss on warrant valuation adjustment of $70,985 and increase interest expense related to notes payable, related parties of $17,222 in 2015.

Provision for Income Taxes

At September 30, 2015, we had federal net operating loss carryforwards of $66,038,028 through the year ended December 31, 2014 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the nine months ended September 30, 2015 was $3,707,492, or ($0.06) per basic and diluted share, compared to a net loss of $5,750,509, or ($0.12) per basic and diluted share, for the same period in 2014, a decrease in the net loss of $2,043,017, or 36%. The decrease in the net loss for 2015 was primarily a result of the reduced operating expenses of $1,619,542 and reduced other expenses of $453,140 as discussed above.

Results of Operations for the Years ended December 31, 2014 and 2013

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2014 were $847,367, compared to $800,029 for the same period in 2013, an increase of $47,338, or 6%. Revenue resulted primarily from sales in Europe, Asia and Asia/Pacific of our dermaPACE and orthoPACE devices and related applicators. The increase in revenue for 2014 is primarily due to an increase in sales of orthoPACE devices in Asia/Pacific, as compared to the prior year, as well as higher sales of refurbished applicators in Europe.

Cost of revenues for the year ended December 31, 2014 were $219,975, compared to $189,791 for the same period in 2013. Gross profit as a percentage of revenues was 74% for the year ended December 31, 2014, compared to 76% for the same period in 2013. The slight decrease in gross profit as a percentage of revenues in 2014 was due to a greater portion of revenues being from the sale of devices in 2014, as compared to 2013, which have a lower margin than applicators.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2014 were $3,000,807, compared to $2,296,662 for the same period in 2013, an increase of $704,145, or 31%. Research and development expenses include the costs associated with the dermaPACE clinical trial, which began the more costly enrollment phase in June 2013 and has continued through 2014, and totaled $1,772,444 and $1,333,741 for the years ended December 31, 2014 and 2013, respectively.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2014 were $3,269,033, as compared to $3,963,206 for the same period in 2013, a decrease of $694,173, or 18%. The decrease in general and administrative expenses in 2014, as compared to 2013, was primarily due a decrease in stock-based compensation due to the forfeiture of stock options granted in February 2013 to the former Chief Executive Officer upon his termination in April 2014 and a decrease in the cost for stock issued for consulting services as a result of less financial and investors relations consultants utilized in 2014 as compared to the prior year.

Depreciation and Amortization

Depreciation for the year ended December 31, 2014 was $14,286, compared to $19,575 for the same period in 2013, a decrease of $5,289, or 27%.

Amortization for the years ended December 31, 2014 and 2013 was $306,756 for each year.

Other Income (Expense)

Other income (expense) was a net expense of $10,590 for the year ended December 31, 2014 as compared to a net expense of $5,978,821 for the same period in 2013, a decrease of $5,968,231 in the net expense. The net expense in 2013 included a non-cash loss of $2,373,813 for the embedded conversion feature of the Senior Secured Notes which were converted to equity during the third quarter of 2013, a non-cash loss on extinguishment of the Senior Secured Notes of $1,073,572 for the fair value of the warrants issued to the note holders, and $2,178,390 in non-cash amortization expense of the debt discount on the embedded conversion feature of the Senior Secured Notes and interest expense on the Senior Secured Notes that was recorded in 2013.

Provision for Income Taxes

At December 31, 2014, we had federal net operating loss carryforwards of $66,038,028 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to

date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the year ended December 31, 2014 was $5,974,080, or ($0.12) per basic and diluted share, compared to a net loss of $11,299,721, or ($0.40) per basic and diluted share, for the same period in 2013, a decrease in the net loss of $5,325,641, or 47%. The decrease in the net loss was primarily a result of the non-cash decrease in the net expense in other income (expense) of $5,968,231 for 2014, as compared to 2013, for the accounting for the Senior Secured Notes which were converted to equity in the third quarter of 2013.

We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device clinical trial for the treatment of diabetic foot ulcers.

Liquidity and Capital Resources

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources to complete our Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers. Because of the significant time it will take to complete the clinical trial process, and for us to obtain approval from regulatory authorities, assuming positive clinical results, and successfully commercialize our product, we will require additional capital resources. We incurred a net loss of $3,707,492 for the nine months ended September 30, 2015 and $5,974,080 for the year ended December 31, 2014. These operating losses create uncertainty about our ability to continue as a going concern.

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2015, we had cash and cash equivalents totaling $625,450. For the nine months ended September 30, 2015 and 2014, the net cash used by operating activities was $3,007,790 and $5,542,192, respectively. Management has obtained two 8% Convertible Promissory Notes totaling $100,000 to fund operations until the Minimum Offering amount is raised. Management expects the cash used in operations for the Company during the first two quarters of 2016 will be approximately $200,000 to $250,000 per month, exclusive of FDA submission costs, as resources are devoted to the review and analysis of the clinical data results phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers and preparation of the submission strategy to the FDA. We will not know the costs for our FDA submissions until after our submission strategy meeting with the FDA, expected to occur in late March or early April.

The continuation of the Company's business is dependent upon raising additional capital before the conclusion of the first quarter of 2016 to fund operations. Management's plans are to obtain additional capital through the issuance of common or preferred stock, securities convertible into common stock or secured or unsecured debt, investments by strategic partner for market opportunities, which may include strategic partnerships or licensing arrangements or complete a joint venture, partnership or sale of the wound product to complete the FDA trial successfully and begin commercialization of the product in 2016. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. The condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

We may also attempt to raise additional capital if there are favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. To the extent that we raise additional funds by issuance of equity securities, our shareholders will experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors

generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones would harm our future capital position.

On May 27, 2014, we received $900,000 as the final payment on the Subscription Agreement with a related party.

On March 17, 2014, we completed a private placement of securities for an aggregate total purchase price of $9,280,000 (the “2014 Private Placement”). In addition, we raised $815,000 through the issuance of unsecured 18% Convertible Promissory Notes in the first quarter of 2014, which by their terms, converted into equity at the same terms as the 2014 Private Placement on March 17, 2014.

For the nine months ended September 30, 2015, net cash used by operating activities was $3,007,790, primarily consisting of compensation costs, research and development activities and general corporate operations.

For the years ended December 31, 2014 and 2013, net cash used by operating activities was $6,678,369 and $3,924,204, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The increase in the use of cash for operating activities for the year ended December 31, 2014, as compared to the same period for 2013, of $2,754,165, or 70%, was primarily due to the increased research and development expenses in 2014, as compared to 2013, of $704,145 and the reduction of accounts payable and accrued expenses in 2014 of $1,197,304. Net cash provided by financing activities for the years ended December 31, 2014 and 2013 was $10,071,149 and $4,035,122, respectively, which in 2014 primarily consisted of the net proceeds from 2014 Private Placement of $8,562,500, net proceeds from sale of capital stock per the Subscription Agreement of $900,000, and proceeds from the 18% Convertible Promissory Notes of $815,000. Net cash provided by financing activities for 2013 primarily consisted of the net proceeds from the subscriptions payable for Senior Secured Notes of $1,570,000, net proceeds from the Public Offering of $1,517,450 and proceeds from the Private Placements of $626,188. Cash and cash equivalents increased by $3,364,756 and $111,990 for the years ended December 31, 2014 and 2013, respectively.

Contractual Obligations

Our major outstanding contractual obligations relate to our operating lease for our facility, purchase and supplier obligations for product component materials and equipment, and our notes payable.

In April 2007, we entered into a lease agreement for the production and research and development office for 5,168 square feet of space. Under the terms of the lease, we pay monthly rent of $9,027, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the lease expired on July 31, 2010, and we extended the lease until October 31, 2015. In October, 2015 we amended the lease agreement to allow us to remain in the space on a month-to-month basis and have started a search for new office space.

We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantities of product component materials for our products through the development, clinical testing and commercialization phases. We have a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our devices.

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, Inc., we issued two notes to HealthTronics, Inc. for $2,000,000 each. The notes bear interest at 6% annually. Quarterly interest through June 30, 2010 was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal is due August 1, 2015. Accrued interest on the notes not payable until August 2015 totaled $1,372,743 at December 31, 2014 and 2013. On June 15, 2015, we entered into an amendment with HeatlhTronics, Inc. to amend certain provisions of the notes payable, related parties. The note amendment provides for the extension of the due date to January 31, 2017. In connection with the note amendment,

we entered into a security agreement with HealthTronics, Inc. to provide a first security interest in our assets. The notes payable, related parties will bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. We will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds we receive through the issuance or sale of any equity securities in cash or through the licensing of our patents or other intellectual property rights.

Recently Issued Accounting Standards

There have been no recently issued accounting standards that are expected to have a material impact on our consolidated financial statements.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Effects of Inflation

Because our assets are, to an extent, liquid in nature, they are not significantly affected by inflation. However, the rate of inflation affects such expenses as employee compensation, office space leasing costs and research and development charges, which may not be readily recoverable during the period of time that we are bringing the product candidates to market. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations.

BUSINESS

Overview

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.

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.

Pulsed Acoustic Cellular Expression (PACE) Technology for Regenerative Medicine

Our PACE product candidates, including our lead product candidate, dermaPACE, deliver high-energy acoustic pressure waves in the shockwave spectrum to produce compressive and tensile stresses on cells and tissue structures. These mechanical stresses at the cellular level have been shown in pre-clinical work to promote angiogenic and positive inflammatory responses, and quickly initiate the healing cascade. This has been shown in pre-clinical work to result in microcirculatory improvement, including increased perfusion and blood vessel widening (arteriogenesis), the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE procedures trigger the initiation of an accelerated inflammatory response that speeds wounds into proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help reinitiate the body's own healing response. We believe that our PACE technology is well suited for various applications due to its activation of a broad spectrum of cellular events critical for the initiation and progression of healing.

High-energy, acoustic pressure waves in the shockwave spectrum are the primary component of our previously developed product, OssaTron, which was approved by the FDA and marketed in the United States for use in chronic tendonitis of the foot in 2000 and the elbow in 2003. Additionally, acoustic shockwaves have been used safely at much higher energy and pulse levels in the lithotripsy procedure (breaking up kidney stones) by urologists for over 25 years and has reached standard of care status.

We research, design, manufacture, market and service our products worldwide and believe we have already 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 orthoPACE, Evotron and OssaTron devices in Europe and Asia.

We believe our experience from our preclinical research and the clinical use of our predecessor legacy devices in Europe and Asia, as well as our OssaTron device in the United States, demonstrates the safety, clinical utility and efficacy of these products. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications.

Currently, there are limited biological or mechanical therapies available to activate the healing and regeneration of tissue, bone and vascular structures. As baby boomers age, the incidence of their targeted diseases and musculoskeletal injuries and ailments will be far more prevalent. We believe that our pre-clinical and clinical studies suggest that our PACE technology will be effective in targeted applications. If successful, we anticipate that future clinical studies, including our dermaPACE clinical study in the United States for treating diabetic foot ulcers, should lead to regulatory approval of our regenerative product candidates in the United States, Europe and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and

noninvasive treatment options in wound healing, orthopedic injuries, plastic/cosmetic uses and cardiac procedures, improving the quality of life for millions of patients suffering from injuries or deterioration of tissue, bones and vascular structures.

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 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 as of April 30, 2014, we had enrolled the minimum number of 90 patients in the clinical trial, which represented the number of patients for the first interim analysis by the independent Data Monitoring Committee (DMC). In September 2014, we reported that the independent Data Monitoring Committee had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the clinical trial and recommended we continue enrollment of patients into the study up to the next predefined patient analysis point of 130 patients. We completed enrollment for the 130 patients in November 2014 and suspended further enrollment at that time.

The DMC performed an analysis of the primary efficacy endpoint of the rate of 100% complete wound closure at the 12-week endpoint for the dermaPACE treated patients as compared to the sham-control patients and the safety data. The DMC has completed its review and noted there were no safety issues. The DMC reported the Monitoring Success Criterion for primary efficacy endpoint of 100% complete wound closure at 12 weeks has not been met and, assuming similar trends for any additional patents enrolled, will likely not be met at the next predefined analysis point of 170 patients. The Monitoring Success Criterion is a predictive probability of dermaPACE achieving statistical significance in the rate of 100% complete wound closure at 12 weeks as compared to the rate for sham-control.

As per its charter, the DMC's review was limited to only the 12-week endpoint data. The DMC has requested to us the ability to review complete closure rates at later points in the study, as patients were followed for up to 24 weeks and the DMC noted we had positive results in the first study of 206 patients completed in 2011 at the 20-week endpoint.

We have retained Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in January 2015 to lead the Company's interactions and correspondence with the FDA for the dermaPACE, which have already commenced. MCRA has successfully worked with the FDA on numerous Premarket Approvals (PMAs) for various musculoskeletal, restorative and general surgical devices since 2006.

We, including our regulatory advisor MCRA, held an in-person meeting with the FDA in June 2015 and in this meeting, it was determined that the best path would be for us to retain the original analysis plan. In addition, the FDA noted the totality of the data from the clinical study, such as additional endpoints and a favorable risk/benefit profile, will play an important role in the FDA's review of our PMA submission.

All 130 of the patients enrolled as of November 2014 have completed the full 24-week follow-up at this time. We worked with our Clinical Research Organization (CRO), CPC Clinical Research, Inc., to complete the auditing of the clinical documentation at each clinical site, perform site close-out visits, complete a final review and then locked the clinical study database in August 2015. We have conducted preliminary statistical analyses and announced that we did not reach statistical significance at 12 weeks, however our clinical study did show efficacy at 20 weeks when combining the two trials. There were no serious or related adverse events associated with dermaPACE treatment reported during the course of the two studies and there were no issues regarding the tolerability of the treatment. Due to the safety profile of our device and the efficacy of the data at 20 weeks, we are moving forward with our PMA submission to the FDA and expect to make our submission in early first quarter of 2016. We will be working with MCRA in developing a submission strategy and to serve as the key element in communication with FDA during the pre and post PMA submission process.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the pivotal trial (discussed below). Similar to the pivotal trial, four (4) dermaPACE procedures are administered during the first two weeks following subject enrollment. In the current trial, however, up to four (4) additional dermaPACE procedures are

delivered bi-weekly, between weeks 4 and 10 following subject enrollment, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical study. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted pivotal study. Bayesian designs are supported by the FDA where there is strong prior evidence that can be incorporated into the clinical study design. By incorporating the prior positive information regarding complete wound closure after one treatment cycle into the design of the current study, substantially fewer patients are required than would otherwise be the case while still ensuring adequate statistical power. This approach saves significant time and preserves scientific rigor.

Our dermaPACE device has received the European CE Mark approval to treat acute and chronic defects of the skin and subcutaneous soft tissue, such as in the treatment of pressure ulcers, diabetic foot ulcers, burns, and traumatic and surgical wounds. We are actively marketing dermaPACE to the European Community, Canada and Asia/Pacific, utilizing distributors in select countries.

Previous clinical work supporting our current dermaPACE clinical study

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 July 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. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

A total of 206 patients entered the dermaPACE study at 24 sites. The patients in the study were followed for a total of 24 weeks. The study's primary endpoint, wound closure, was defined as "successful" if the skin was 100% reepithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits.

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) sham-control subjects.
- In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of sham-control subjects (p=0.047); in the efficacy evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of sham-control subjects (p=0.018).
- Subjects treated with dermaPACE achieved a significant increase in the rate of complete and/or ≥90% wound closure. We analyzed a clinically relevant ≥ 90% wound closure endpoint that demonstrated statistical significance (p=0.0161) in favor of dermaPACE subjects (51/107, 48%) compared to patients randomized to receive sham-control (31/99, 31%).
- Within 6 weeks following the initial dermaPACE treatment, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control ($p<0.05$).
- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20.0% in the sham-control group.
- Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

We filed with the FDA the clinical module of the dermaPACE PMA application in June 2011. 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. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

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.

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Our primary interest is obtaining FDA approval for our lead product candidate, dermaPACE, for the wound care market, initially in the United States for treating diabetic foot ulcers. Diabetes is common, disabling and deadly. In the United States, diabetes has reached epidemic proportions. According to the American Diabetes Association, about 29.1 million people (9.3% of the total United States population) have diabetes, and more than one and a half million new cases are diagnosed in people aged 20 years or older each year. If current prediabetes statistics are an indication, 1 in 3 Americans will develop diabetes at some point in their lifetime, and those with diabetes had about a 1.5 times higher death rate than those without diagnosed diabetes. Importantly, up to 25% of people with diabetes will develop a diabetic foot ulcer, resulting in 3 million diabetic foot ulcers annually in the United States alone. Diabetes puts tremendous economic pressure on the United States healthcare system. In March 2013, the Centers for Disease Control and Prevention (CDC) reported the total costs (direct and indirect) of diabetes in the United States is $245 billion annually, and people with diagnosed diabetes have medical expenditures that are over two times higher than medical expenditures for people without diabetes. Incremental healthcare costs alone are $11,000 to $17,000 for a patient with a diabetic foot ulcer, due to more days hospitalized, more days requiring home healthcare, more emergency department visits and more outpatient/physician office visits. In addition, direct and indirect costs of an amputation average over $70,000 per patient. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need globally, yet in short supply. According to the International Diabetes Federation, by the year 2035 the prevalence of diabetes is expected to rise by 55% to 592 million people worldwide.

A majority of challenging wounds are non-healing chronic wounds. These wounds often involve physiologic, complex and multiple complications such as reduced blood supply, compromised lymphatic systems or immune deficiencies that interfere with the body’s normal wound healing processes. In addition, diabetic ulcers and pressure ulcers are often slow-to-heal wounds. These wounds often develop due to a patient’s impaired vascular and tissue repair capabilities. These conditions can also inhibit a patient’s healing process, and often fail to heal for many months, and sometimes, for several years. Wounds that are difficult to treat do not always respond to traditional therapies, which include hydrocolloids, hydrogels and alginates, among other treatments. We believe that physicians and hospitals need a therapy that addresses the special needs of these wounds with high levels of both clinical and cost effectiveness.

We believe we are developing a safe and advanced technology in the wound healing and tissue regeneration market with PACE. dermaPACE is noninvasive and does not require anesthesia, making it a cost-effective, time-efficient and painless approach to wound care. Physicians and nurses look for therapies that can accelerate the healing process and overcome the obstacles of patients’ compromised conditions, and prefer therapies that are easy to administer. In addition, since many of these patients are not confined to bed, healthcare providers want therapies that are minimally disruptive to the patient’s or the caregiver’s daily routines. dermaPACE’s noninvasive treatment is designed to elicit the body’s own healing response. dermaPACE’s noninvasive treatments, followed by simple standard of care dressing changes, are designed to allow for limited disruption to the patients’ normal lives and have no effect on mobility while their wounds heal.

Developing Product Opportunities - Orthopedic

We launched the orthoPACE device in Europe, which is intended for use in orthopedic, trauma and sports medicine indications, following CE Marking in 2010. The device features four types of applicators including a unique applicator that is less painful for some indications and may reduce or completely eliminate anesthesia for some patients. In the orthopedic setting, the orthoPACE is being used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs.

We believe there are significant opportunities in the worldwide orthopedic market, 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.

We have experience in the sports medicine field (which generally refers to the non-surgical and surgical management of cartilage, ligament and tendon injuries) through our legacy devices, OssaTron and Evotron. Common examples of these injuries include extremity joint pain, torn rotator cuffs (shoulder), tennis elbow, Achilles' tendon tears and torn meniscus cartilage in the knee. Injuries to these structures are very difficult to treat because the body has a limited natural ability to regenerate these tissues. Cartilage, ligament and tendons seldom return to a pre-injury state of function. Due to a lack of therapies that can activate healing and regenerate these tissues, many of these injuries will result in a degree of permanent impairment and chronic pain. Prior investigations and pre-clinical work indicate that PACE can activate various cell types and may be an important adjunct to the management of sports medicine injuries.

Trauma injuries are acute and result from any physical damage to the body caused by violence or accident or fracture. Surgical treatment of traumatic fractures often involves fixation with metallic plates, screws and rods (internal fixation) and include off-loading to prevent motion, permitting the body to initiate a healing response. In the United States, six million traumatic fractures are treated each year, and over one million internal fixation procedures are performed annually. The prevalence of non-union among these fractures is between 2.5% and 10.0% depending on the fracture type and risk factors such as diabetes and smoking history or other systemic diseases. At the time of surgery, adjunctive agents (such as autograft, cadaver bone and synthetic filling materials) are often implanted along with internal fixation to fill bony gaps or facilitate the healing process to avoid delayed union or non-union (incomplete fracture healing) results. Both pre-clinical and clinical investigations have shown positive results, suggesting our technology could potentially be developed as an adjunct to these surgeries or primary treatment protocol for delayed or non-union events.

Non-Medical Uses For Our Shockwave Technology

We believe there are significant license/partnership opportunities for our shockwave technology in non-medical uses, including in the energy, water, food and industrial markets.

Due to their powerful pressure gradients and localized cavitational effects, we believe high-energy, acoustic pressure shockwaves can be used to clean, in an energy efficient manner, contaminated fluids and hard surfaces from impurities, bacteria, viruses and other harmful micro-organisms, which provides opportunities for our technology in cleaning industrial and domestic/municipal waters or cleaning of any surface such as floors, walls, etc. Based on the same principles of action of the shockwaves against bacteria, viruses and harmful micro-organisms, we believe our technology can be applied for cleaning or sterilization of various foods such as milk, natural juices and meats.

In the energy sector, we believe shockwaves can be used to improve oil recovery (IOR), as a supplement to or in conjunction with existing fracking technology, which utilizes high pressurized water/gases to crack the rocks that trap oil in the underground reservoir. The use of our high-energy, acoustic pressure shockwaves could improve the efficiency and reduce the environmental impact of the fracking process. Furthermore, we believe our technology can be used for enhanced oil recovery (EOR) based on the changes in fluid flow characteristics resulting from shockwave stimulation, as a tertiary method of oil recovery from older oil fields.

Additionally, we demonstrated through a study performed at Montana State University that high-energy, acoustic pressure shockwaves are disrupting biofilms and thus can be used for surface cleaning or to unclog pipes in the energy industry (shore or off-shore installations), food industry and water management industry, which will reduce or eliminate down times with significant financial benefits for maintenance of existing infrastructure.

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 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.

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 enrollment of 130 patients was completed in November 2014. Management has completed the preliminary analysis phase of the clinical study data and plans to submit the PMA to the FDA in early 2016 with expected FDA approval in late 2016.

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.

Scientific Advisors

We have established a network of advisors that brings expertise in wound healing, orthopedics, cosmetics, clinical and scientific research, and FDA experience. We consult our scientific advisors on an as-needed basis on clinical and pre-clinical study design, product development, and clinical indications.

We pay consulting fees to certain members of our scientific advisory board for the services they provide to us, in addition to reimbursing them for incurred expenses. The amounts vary depending on the nature of the services. We paid our advisors aggregate consulting fees through the issuance of stock options in 2014 and 2013 and recorded stock-based compensation expense of $35,625 and $64,000 for the years ended December 31, 2014 and 2013, respectively.

Sales, Marketing and Distribution

We do not have any commercial products available for sale in the United States. We currently do not have the sales or marketing resources required to commercialize our products in the United States. Following FDA approval, we intend to seek a development and/or commercialization partnership, or to commercialize a product ourselves. Outside the United States, we retain distributors to represent our products in selective international markets. These distributors have been selected based on their existing business relationships and the ability of their sales force and distribution capabilities to effectively penetrate the market with our PACE product line. We rely on these distributors to manage physical distribution, customer service and billing services for our international customers.

Manufacturing

We have developed a network of suppliers, manufacturers and contract service providers to provide sufficient quantities of our products.

We are party to a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our products. Our generator boxes are manufactured in accordance with applicable quality standards (EN ISO 13485) and applicable industry and regulatory standards. We produce the applicators and applicator kits for our products. In addition, we program and load software and perform the final product testing and certifications internally for all of our devices.

Our facility in Alpharetta, Georgia consists of 5,168 square feet and provides office, research and development, quality control, production and warehouse space. It is a FDA registered facility and is ISO 13485 certified (for meeting the requirements for a comprehensive management system for the design and manufacture of medical devices).

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing upon our proprietary rights. We seek to protect our proprietary position by, among other methods, filing United States and selected foreign patent applications and United States and selected foreign trademark applications related to our proprietary technology, inventions, products and improvements that are important to the development of our business. Effective trademark, service mark, copyright, patent and trade secret protection may not be available in every country in which our products are made available. The protection of our intellectual property may require the expenditure of significant financial and managerial resources.

Patents

We consider the protection afforded by patents important to our business. We intend to seek and maintain patent protection in the United States and select foreign countries where deemed appropriate for products that we develop. There are no assurances that any patents will result from our patent applications, or that any patents that may be issued will protect our intellectual property, or that any issued patents or pending applications will not be successfully challenged, including as to ownership and/or validity, by third parties. In addition, if we do not avoid infringement of the intellectual property rights of others, we may have to seek a license to sell our products, defend an infringement action or challenge the validity of intellectual property in court. Any current or future challenges to our patent rights, or challenges by us to the patent rights of others, could be expensive and time consuming.

We derive our patent rights, including as to both issued patents and “patent pending” applications, from three sources: (1) assignee of patent rights in technology we developed; (2) assignee of patent rights purchased from HealthTronics, Inc. (“HealthTronics”); and (3) as licensee of certain patent rights assigned to HealthTronics. In August 2005, we purchased a majority of our current patents and patent applications from HealthTronics, to whom we granted back perpetual and royalty-free field-of-use license rights in the purchased patent portfolio primarily for urological uses. We believe that our owned and licensed patent rights provide a competitive advantage with respect to others that might seek to utilize certain of our apparatuses and methods incorporating extracorporeal shockwave technologies that we have patented; however, we do not hold patent rights that cover all of our products, product components, or methods that utilize our products. We also have not conducted a competitive analysis or valuation with respect to our issued and pending patent portfolio in relation to our current products and/or competitor products.

We are the assignee of twenty-five issued United States patents and fourteen issued foreign patents which on average have remaining useful lives of ten years or longer. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations, piezoelectric fiber shockwave devices, chemical components for shockwave generation and detachable therapy heads with data storage. Our United States patents also include patent claims directed to methods of using acoustic shockwaves, including shockwave devices such as our products, to treat ischemic conditions, spinal cord scar tissue and spinal injuries, body tissues under positive pressure, bone surface gaps, and, within particular treatment parameters, diabetic foot ulcers and pressure sores. While such patented method claims may provide patent protection against certain indirect infringing promotion and sales activities of competing manufacturers and distributors, certain medical methods performed by medical practitioners or related health care entities may be subject to exemption from potential infringement claims under 35 U.S.C. § 287(c) and, therefore, may limit enforcement of claims of our method patents as compared to device and non-medical method patents.

We also currently maintain six United States non-provisional patent applications, three provisional patent applications and four foreign patent applications. Our patent-pending rights include inventions directed to certain shockwave devices and systems, ancillary products and components for shockwave treatment devices, and various methods of using acoustic pressure waves. Such patent-pending methods include, for example, using acoustic pressure waves to treat soft tissue disorders, bones, joints, wounds, skin, blood vessels and circulatory disorders, lymphatic disorders, cardiac tissue, fat and cellulite, cancer, blood and fluids sterilization, and to destroy pathogens. All of our United States and foreign pending applications either have yet to be examined or require response to an examiner's office action rejections and, therefore, remain subject to further prosecution, the possibility of further rejections and appeals, and/or the possibility we may elect to abandon prosecution, without assurance that a patent may issue from any pending application.

Under our license to HealthTronics, we reserve exclusive rights in our purchased portfolio as to orthopedic, tendonopathy, skin wounds, cardiac, dental and neural medical conditions and to all conditions in animals (Ortho Field). HealthTronics receives field-exclusive and sublicensable rights under the purchased portfolio as to (1) certain HealthTronics lithotripsy devices in all fields other than the Ortho Field, and (2) all products in the treatment of renal, ureteral, gall stones and other urological conditions (Litho Field). HealthTronics also receives non-exclusive and non-sublicensable rights in the purchased portfolio as to any products in all fields other than the Ortho Field and Litho Field.

Pursuant to mutual amendment and other assignment-back rights under the patent license agreement with HealthTronics, we are also a licensee of certain patents and patent applications that have been assigned to HealthTronics. We received a perpetual, non-exclusive and royalty-free license to nine (9) issued foreign patents. Our non-exclusive license is subject to HealthTronics' sole discretion to further maintain any of the patents and pending applications assigned back to HealthTronics.

As part of the sale of the veterinary business in June 2009, we have also granted certain exclusive and non-exclusive patent license rights to Pulse Veterinary Technologies, LLC under most of our patent portfolio issued before 2009 to utilize shockwave technologies in the field of non-human mammals.

Given our international patent portfolio, there are growing risks of challenges to our existing and future patent rights. Such challenges may result in invalidation or modification of some or all of our patent rights in a particular patent territory, and reduce our competitive advantage with respect to third party products and services. Such challenges may also require the expenditure of significant financial and managerial resources.

If we become involved in future litigation or any other adverse intellectual property proceeding, for example, as a result of an alleged infringement, or a third party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, including treble damages, invalidation of our intellectual property and injunctive relief that could prevent us

from using technologies or developing products, any of which could have a significant adverse effect on our business, financial condition and results of operation. In addition, any claims relating to the infringement of third party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation or lengthy governmental proceedings and could divert management's attention and resources and require us to enter into royalty or license agreements which are not advantageous, if available at all.

Trademarks

Since other products on the market compete with our products, we believe that our product brand names are an important factor in establishing and maintaining brand recognition.

We have the following trademark registrations: SANUWAVE® (United States, European Community, Canada, Japan, Switzerland, Taiwan and under the Madrid Protocol), dermaPACE® (United States, European Community, Japan, South Korea, Switzerland, Taiwan and under the Madrid Protocol), angioPACE® (Australia, European Community and Switzerland), PACE® (United States, European Community, China, Hong Kong, Singapore, Switzerland, Taiwan), orthoPACE® (United States and European Community), DAP® (United States) and Profile™ (United States, European Community and Switzerland).

We also maintain trademark registrations for: OssaTron® (United States and Germany), evoPACE® (Australia, European Community and Switzerland), Evotron® (Germany and Switzerland), Evotrode® (Germany and Switzerland), HMT® (Switzerland), Orthotripsy® (United States), Reflectron® (Germany and Switzerland), Reflectrode® (Germany and Switzerland), CSWT® (Switzerland), OSWT® (Switzerland) and TSWT® (Switzerland).

We have filed pending trademark applications for: dermaPACE™ (Canada), and PACE™ (Canada).

Potential Intellectual Property Issues

Although we believe that the patents and patent applications, including those that we license, provide a competitive advantage, the patent positions of biotechnology and medical device companies are highly complex and uncertain. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Our success will depend in part on us not infringing on patents issued to others, including our competitors and potential competitors, as well as our ability to enforce our patent rights. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products and product candidates, or to obtain and use information that we regard as proprietary. In enforcement proceedings in Switzerland, we are currently assisting HealthTronics as an informer of misappropriation by SwiTech and related third parties of intellectual property rights in legacy proprietary software and devices relating to assets we purchased from HealthTronics in August 2005. Such present or future actions against violations of our intellectual property rights may result in us incurring material expense and divert the attention of management.

Third parties that license our proprietary rights, such as trademarks, patented technology or copyrighted material, may also take actions that diminish the value of our proprietary rights or reputation. In addition, the steps we take to protect our proprietary rights may not be adequate and third parties may infringe or misappropriate our copyrights, trademarks, trade dress, patents and similar proprietary rights.

We collaborate with other persons and entities on research, development and commercialization activities and expect to do so in the future. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, researchers, licensors, licensees and consultants. In addition, other parties may circumvent any proprietary protection that we do have. As a result, we may not be able to maintain our proprietary position.

Competition

We believe the advanced wound care market can benefit from our technology which up-regulates the biological factors that promote wound healing. Current technologies developed by Kinetic Concepts, Inc. ("KCI"), Organogenesis, Inc., Smith & Nephew plc, Derma Sciences, Inc., Molnlycke Health Care, and Systagenix Wound Management (US), Inc. manage wounds, but, in our opinion, do not provide the value proposition to the patients and care givers like our PACE technology has the potential to do. The leading medical device serving this market is the Vacuum Assisted Closure ("V.A.C.") System marketed by KCI. The V.A.C. is a negative pressure wound therapy device that applies suction to debride and manage wounds.

There are also several companies that market extracorporeal shockwave device products targeting lithotripsy and orthopedic markets, including Dornier MedTech, Storz Medical AG and Tissue Regeneration Technologies, LLC, and could ultimately pursue the wound care market. Nevertheless, we believe that dermaPACE has a competitive advantage over all of these existing technologies by achieving wound closure by means of a minimally invasive process through innate biological response to PACE.

Developing and commercializing new products is highly competitive. The market is characterized by extensive research and clinical efforts and rapid technological change. We face intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major pharmaceutical companies. We may be unable to respond to technological advances through the development and introduction of new products. Most of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources. These competitors may also be in the process of seeking FDA or other regulatory approvals, or patent protection, for new products. Our competitors may commercialize new products in advance of our products. Our products also face competition from numerous existing products and procedures, which currently are considered part of the standard of care. In order to compete effectively, our products will have to achieve widespread market acceptance.

Regulatory Matters

FDA Regulation

Each of our products must be approved or cleared by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our product candidates are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products.

In the United States, the FDA subjects medical products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products, and we may be criminally prosecuted. Failure to comply with the law could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension or withdrawal of product approval, injunctions, or criminal prosecution.

The FDA has determined that our technology and product candidates constitute “medical devices.” The FDA determines what center or centers within the FDA will review the product and its indication for use, and also determines under what legal authority the product will be reviewed. For the current indications, our products are being reviewed by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case the governmental review requirements could vary in some respects.

FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy:

Class I: general controls, such as labeling and adherence to quality system regulations;
Class II: special controls, pre-market notification (510(k)), specific controls such as performance standards, patient registries, and postmarket surveillance, and additional controls such as labeling and adherence to quality system regulations; and
Class III: special controls and approval of a pre-market approval ("PMA") application.

Each of our product candidates require FDA authorization prior to marketing, by means of either a 510(k) clearance or a PMA approval. We are currently proceeding on the basis that dermaPACE is a Class III device requiring a PMA approval. To date, we have corresponded with the FDA pertaining to possible reclassification of PACE technology for certain indications within the Class II designation. The FDA continues to maintain that PACE should remain a Class III technology. Reclassification of the technology is possible but the path through the FDA for such reclassification will be lengthy and involved.

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device, has the same intended use, and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than does a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then a company must submit and the FDA must approve a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with Quality System Regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances where the FDA has not. If the FDA finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

During the review of either a PMA application or 510(k) submission, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. We cannot be sure that our product candidates will be approved or cleared in a timely fashion or at all. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

We do not anticipate device regulatory pathways via the 510(k) route with our current technology. The FDA continues to stress that our products remain Class III, thus requiring the PMA approval pathway. In the past, the 510(k) pathway for product marketing required only the proof of significant equivalence in technology for a given indication with a previously cleared device. Currently, there has been a trend of the FDA requiring additional clinical work to prove

efficacy in addition to technological equivalence. Thus, no matter which regulatory pathway we may take in the future towards marketing products in the United States, we will be required to provide clinical proof of device effectiveness.

Within the past few years, the FDA has released guidelines for the FDA's reviewers to use during a product's submission review process. This guidance provides the FDA reviewers with a uniform method of evaluating the benefits verses the risks of a device when used for a proposed specific indication. Such a benefit/risk evaluation is very useful when applied to a novel device or to a novel indication and provides the FDA with a consistent tool to document their decision process. While intended as a guide for internal FDA use, the public availability of this guidance allows medical device manufacturers to use the review matrix to develop sound scientific and clinical backup to support proposed clinical claims and to help guide the FDA, through the decision process, to look at the relevant data. We intend to use this benefit/risk tool in our FDA submissions.

Obtaining medical device clearance, approval, or licensing in the United States or abroad can be an expensive process. The fees for submitting an original PMA to the FDA for consideration of device approval are substantial. Fees for supplement PMA's are less costly but still can be substantial. International fee structures vary from minimal to substantial, depending on the country. In addition, we are subject to annual establishment registration fees in the United States and abroad. Device licenses require periodic renewal with associated fees as well. In the United States, there is an annual requirement for submitting device reports for Class III/PMA devices, along with an associated fee. Currently, we are registered as a Small Business Manufacturer with the FDA and as such are subject to reduced fees. If, in the future, our revenues exceed a certain annual threshold limit, we may not qualify for the Small Business Manufacturer reduced fee amounts and will be required to pay full fee amounts.

Clinical Trials of Medical Devices

One or more clinical trials are almost always required to support a PMA application and more recently are becoming necessary to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board (IRB) has approved the study.

During the study, the sponsor must comply with the FDA's IDE requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. We, the FDA, or the IRB at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

Post-Approval Regulation of Medical Devices

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- the FDA Quality Systems Regulation (QSR), which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experiences associated with use of the product.

We continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories.

International sales of medical devices manufactured in the United States that are not approved or cleared by the FDA are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Exported devices may also fall under the jurisdiction of the United States Department of Commerce/Bureau of Industry and Security and compliance with export regulations may be required for certain countries.

Manufacturing cGMP Requirements

Manufacturers of medical devices are required to comply with FDA manufacturing requirements contained in the FDA's current Good Manufacturing Practices (cGMP) set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-PMA approval inspection before we can use it. We and some of our third party service providers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

The primary regulatory environment in Europe is the European Union, which consists of 28 member states encompassing most of the major countries in Europe. In the European Union, the European Medicines Agency (EMA) and the European Union Commission have determined that dermaPACE, orthoPACE, OssaTron and Evotron will be regulated as medical device products. These devices have been determined to be Class IIb devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area.

The primary regulatory body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have an ISO 13485:2003 certification, as well as meet additional requirements of Canadian laws. We currently maintain this certification. We maintain a device license for dermaPACE with Health Canada for the indication of "devices for application of shockwaves (pulsed acoustic waves) on acute and chronic defects of the skin and subcutaneous soft tissue".

The primary regulatory bodies and paths in Asia and Australia are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice (GMP), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with GMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

United States Anti-Kickback and False Claims Laws

In the United States, there are Federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in Federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. Other provisions of Federal and state laws provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, certain states have implemented regulations requiring medical device and pharmaceutical companies to report all gifts and payments over $50 to medical practitioners. This does not apply to instances involving clinical trials. Although we intend to structure our future business relationships with clinical investigators and purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by Federal or state enforcement officials under these laws.

Third Party Reimbursement

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers' compensation plans. These third party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been approved or cleared by the FDA for commercial distribution, we may find limited demand for the device until adequate reimbursement has been obtained from governmental and private third party payers.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third party payers, that an adequate level of reimbursement will be available or that the third party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use products, including ours.

One of the components in the reimbursement decision by most private insurers and governmental payers, including the Centers for Medicare & Medicaid Services, which administers Medicare, is the assignment of a billing code. Billing codes are used to identify the procedures performed when providers submit claims to third party payers for reimbursement for medical services. They also generally form the basis for payment amounts. We will seek new billing codes for the wound care indications of our products as part of our efforts to commercialize such products.

The initial phase of establishing a professional billing code for a medical service typically includes applying for a CPT Category III code. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as American Medical Association (AMA) CPT Editorial Panel review. A new CPT Category III code will be assigned if the AMA CPT Editorial Panel committee deems it meets the applicable criteria and is appropriate. In 2011, we received two CPT Category III codes for extracorporeal shock wave therapy (ESWT) in wound healing.

The secondary phase in the CPT billing code process includes the establishment of a permanent CPT Category I code in which relative value is analyzed and established by the AMA. The approval of this code, is based on, among other criteria, widespread usage and established clinical efficacy of the medical service.

There are also billing codes that facilities, rather than health care professionals, utilize for the reimbursement of operating costs for a particular medical service. For the hospital outpatient setting, the Centers for Medicare & Medicaid Services automatically classified the new ESWT wound healing CPT Category III codes into interim APC groups. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment.

We believe that the overall escalating costs of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. In addition, recent healthcare reform measures, as well as legislative and regulatory initiatives at the Federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third party payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

Environmental and Occupational Safety and Health Regulations

Our operations are subject to extensive Federal, state, provincial and municipal environmental statutes, regulations and policies, including those promulgated by the Occupational Safety and Health Administration, the United States Environmental Protection Agency, Environment Canada, Alberta Environment, the Department of Health Services, and the Air Quality Management District, that govern activities and operations that may have adverse environmental effects such as discharges into air and water, as well as handling and disposal practices for solid and hazardous wastes. Some of these statutes and regulations impose strict liability for the costs of cleaning up, and for damages resulting from, sites of spills, disposals, or other releases of contaminants, hazardous substances and other materials and for the investigation and remediation of environmental contamination at properties leased or operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. In addition, we may be subject to claims

and lawsuits brought by private parties seeking damages and other remedies with respect to similar matters. We have not to date needed to make material expenditures to comply with current environmental statutes, regulations and policies. However, we cannot predict the impact and costs those possible future statutes, regulations and policies will have on our business.

Research and Development

For the years ended December 31, 2014 and 2013, we spent $3,000,807 and $2,296,662, respectively, on research and development activities which primarily consist of clinical trial expenses for the dermaPACE diabetic foot ulcer clinical study in the United States.

Employees

As of February 12, 2016, we had a total of seven full time employees in the United States. Of these, five were engaged in research and development which includes clinical, regulatory and quality. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

Properties

Our operations, production and research and development office is in a leased facility in Alpharetta, Georgia, consisting of 5,168 square feet of space under a lease which expired on October 31, 2015. We have amended the lease to remain in the space on a month-to-month basis. Under the terms of the original lease, we paid monthly rent of $8,760, subject to adjustment on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. Under the terms of the amended lease, we pay monthly rent at 125% of current rent for the first two months and at 150% of current rent for each month thereafter.

Legal Proceedings

There are no material pending legal proceedings to which we are a party or of which any of our properties are subject; nor are there material proceedings known to us to be contemplated by any governmental authority.

There are no material proceedings known to us, pending or contemplated, in which any of our directors, officers or affiliates or any of our principal security holders, or any associate of any of the foregoing, is a party or has an interest adverse to us.

MANAGEMENT, EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE

Below are the names and certain information regarding the Company’s executive officers and directors.

Name	Age	Position Held
Kevin A. Richardson, II	47	Director, Chairman and Acting Chief Executive Officer
Lisa Sundstrom	46	Chief Financial Officer
John F. Nemelka	48	Director
Alan L. Rubino	59	Director

Kevin A. Richardson, II joined the Company as chairman of the board of directors in October of 2009 and joined SANUWAVE, Inc. as chairman of the board of directors in August of 2005. In November 2012, upon the resignation of the Company's former President and Chief Executive Officer, Christopher M. Cashman, Mr. Richardson assumed the role of Active Chief Executive Officer, in addition to remaining Chairman of the Board, through the hiring of Mr. Chiarelli in February 2013. In April 2014, Mr. Richardson assumed the role of Co-Chief Executive Officer. When Mr. Chiarelli departed the Company in 2014, Mr. Richardson again assumed the role as Acting Chief Executive Officer. Mr. Richardson brings to our board of directors a broad array of financial knowledge for healthcare and other industries. Since 2004, Mr. Richardson has served as managing partner of Prides Capital LLC, an investment management firm.

Lisa Sundstrom joined the Company as Controller in October of 2006, and in August of 2015, assumed the responsibilities of Interim Chief Financial Officer. In December 2015, Ms. Sundstrom was promoted to Chief Financial Officer. Ms. Sundstrom has extensive financial accounting experience with Automatic Data Processing (ADP) and Mitsubishi Consumer Electronics. She began her career with a small public accounting firm, Carnevale & Co., P.C., was Senior Accountant at Mitsubishi Consumer Electronics responsible for the close process and was Accounting Manager for the Benefit Services division of ADP and assisted in the documentation of internal controls for Sarbanes-Oxley compliance. Ms. Sundstrom holds a Bachelor of Science in Accounting from the State University of New York at Geneseo.

John F. Nemelka joined the Company as a member of the board of directors in October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Nemelka founded NightWatch Capital Group, LLC, an investment management business, and has served as its Managing Principal since its incorporation in July 2001. From 1997 to 2000, he was a Principal at Graham Partners, a private investment firm and affiliate of the privately-held Graham Group. From 2000 to 2001, Mr. Nemelka was a Consultant to the Graham Group. Mr. Nemelka brings to our board of directors a diverse background with both financial and operations experience. He holds a B.S. degree in Business Administration from Brigham Young University and an M.B.A. degree from the Wharton School at the University of Pennsylvania.

Alan L. Rubino joined the Company as a member of the board of directors in September of 2013. Mr. Rubino has served as President and Chief Executive Officer of Emisphere Technologies, Inc. since September, 2012. Previously, Mr. Rubino served as the CEO and President of New American Therapeutics, Inc., CEO and President of Akrimax Pharmaceuticals, LLC., and President and COO of Pharmos Corporation. Mr. Rubino has continued to expand upon a highly successful and distinguished career that included Hoffmann-La Roche Inc. where he was a member of the U.S. Executive and Operating Committees and a Securities and Exchange Commission (SEC) corporate officer. During his Roche tenure, he held key executive positions in marketing, sales, business operations, supply chain and human resource management, and was assigned executive committee roles in marketing, project management, and

globalization. Mr. Rubino also held senior executive positions at PDI, Inc. and Cardinal Health. He holds a BA in economics from Rutgers University with a minor in biology/chemistry and completed post-graduate educational programs at the University of Lausanne and Harvard Business School. Mr. Rubino serves on the boards of Aastrom Biosciences, Inc. and Genisphere, LLC and is also on the Rutgers University Business School Board of Advisors.

Summary Compensation Table for Fiscal Years 2015 and 2014

The following table provides certain information concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2015 and 2014.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)[4]	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II Chairman of the Board and Acting Chief Executive Officer (principal executive officer)	2015	$120,000[1]	-	$79,524[3]	-	-	-	-	$199,524
	2014	$90,000[1]	-	-	-	-	-	-	$90,000
Barry J. Jenkins Chief Financial Officer and COO	2015	$143,160[2]	-	-	-	-	-	$ 10,234	$153,394
	2014	$245,417	-	$23,833[3]	-	-	-	$ 18,178	$287,428
Peter Stegano Vice President, Operations	2015	$200,000	-	$53,016[3]	-	-	-	$ 13,852	$266,868
	2014	$189,000	-	$23,833[3]	-	-	-	$ 17,962	$230,795
Iulian Cioanta Vice President, Research and Development	2015	$200,000	$ -	$53,016[3]	-	-	-	$ 17,514	$270,530
	2014	$181,375	$ -	$23,833[3]	-	-	-	$ 18,103	$223,311

(1) Mr. Richardson has been the Company's Chairman of the Board since the Company's inception. In April 2014, Mr. Richardson assumed the role of Co-Chief Executive Officer and was paid $10,000 per month thereafter.
(2) Mr. Jenkins resigned as Chief Financial Officer and COO as of July 31, 2015.
(3) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10.
(4) Includes health, dental, life and disability insurance premiums and 401(k) matching contributions.

Compensation Related Agreements

Barry J. Jenkins

Employment Agreement

General Terms. Pursuant to an employment agreement with the Company's former Chief Financial Officer, Mr. Jenkins agreed to serve as the Chief Financial Officer of the Company commencing on April 10, 2006 and with no specific duration. Mr. Jenkins was entitled to an annual base salary of $205,000, with a performance and compensation review not less often than annually, at which time compensation may be adjusted as determined by the board of directors. With respect to each full fiscal year, Mr. Jenkins was eligible to earn an annual bonus award of 40% of his annual base salary based on the achievement of certain performance goals established by the board of directors and generally consistent with the Company's budget and performance goals established for other management employees. Mr. Jenkins was also entitled to participate in the Company's employee benefit plans (other than annual bonus and incentive plans). The employment agreement contains an agreement not to compete, which covers two years after the term of employement, and a confidentiality provision, which is indefinite. Mr. Jenkins is no longer employed by the Company as of July 31, 2015.

Equity Arrangements. Upon the execution of his employment agreement, Mr. Jenkins was granted options to purchase 104,677 shares of Common Stock, at an exercise price of $2.92 per share. The options vested and became exercisable in four equal installments on April 10, 2007, 2008, 2009 and 2010. Upon the execution of his employment agreement and his commencement of employment, Mr. Jenkins purchased 35,089 shares of Common Stock, at a purchase price of $2.92 per share. In addition, upon the execution of his employment agreement, Mr. Jenkins was granted three supplemental options to purchase Common Stock. The terms of the supplemental options were amended on September 15, 2009. The first and second supplemental options each provided him with the right to purchase 34,778 shares of Common Stock and the third supplemental option provided him with the right to purchase 52,166 shares of Common Stock. The initial exercise price of the supplemental options is $2.92 per share. The supplemental options were fully vested on April 10, 2012.

Joseph Chiarelli

Employment Agreement

General Terms. Joseph Chiarelli is the former Chief Executive Officer and is a former director of the Company. Mr. Chiarelli joined the Company to serve as the Chief Executive Officer and a director of the Company commencing on February 25, 2013 with a two year term thereafter extendable for one year periods. Mr. Chiarelli is no longer employed by the Company as of April 15, 2014 and resigned as a director as of July 31, 2014.

Pursuant to the terms of his former employment agreement, Mr. Chiarelli was entitled to an annual base salary of $200,000 for the first year and $225,000 thereafter, with a performance and compensation review not less often than annually, at which time his compensation was subject to adjustment as determined by the board of directors.

In the event of the satisfaction of the following milestones, the Company was required to award and pay to Mr. Chiarelli a cash bonus as follows: (i) $35,000 for the Company completing a financing resulting in gross proceeds to the Company of no less than $5.0 million at a price per share of not less than $0.35; (ii) $25,000 when the final patient is enrolled in the Company's dermaPACE Phase III clinical trial; (iii) $25,000 upon receipt by the Company of FDA approval for the use of dermaPACE; and (iv) $25,000 upon the execution by the Company of a license or distribution agreement from which the Company is entitled to receive gross proceeds of no less than $1.0 million and the Company has received payments of at least $250,000. In addition, with respect to each full fiscal year, Mr. Chiarelli was eligible to earn an annual bonus award as determined by the board of directors based on the achievement of certain performance goals established by the board of directors. Mr. Chiarelli was also entitled to participate in the Company's employee benefit plans (other than annual bonus and incentive plans). The employment agreement contains an agreement not to compete, which covers two years after the term of employment , and a confidentiality provision, which is indefinite.

Equity Arrangements. Upon the execution of his employment agreement, Mr. Chiarelli was granted options to purchase 2,250,000 shares of the Company's common stock, $0.001 par value, at an exercise price of $0.35 per share. The options vest and become exercisable in five installments as follows: (i) 375,000 vested at grant; (ii) 375,000 vest upon the Company completing a financing resulting in gross proceeds to the Company of no less than $5.0 million at a price per share of not less than $0.35; (iii) 375,000 upon the execution by the Company of a license or distribution agreement from which the Company is entitled to receive gross proceeds of no less than $1.0 million and the Company has received payments of at least $250,000; (iv) 375,000 vest upon receipt by the Company of FDA approval for the use of dermaPACE; and (v) 750,000 vest in the event the Company achieves the milestones (i), (ii), (iii) and (iv) above during the initial two year term and the term is not extended by the Company. Upon his termination on April 15, 2014, the remaining unvested options totaling 1,500,000 shares were forfeited.

Settlement Agreement. On August 13, 2015, Mr. Chiarelli and the Company entered into a confidential settlement agreement in response to an action filed against the Company by Mr. Chiarelli. The settlement agreement contains the entire understanding and complete agreement of the parties involved with respect to the circumstances, matters, events and transactions that were a subject of the action.

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (previously defined as the "*Stock Incentive Plan*"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of Common Stock. Options granted may include nonstatutory options as well as qualified incentive stock options. The Stock Incentive Plan is currently administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are nonstatutory options which vest over a period of up to four years, and have a maximum ten year term. The options are granted at an exercise price equal to the fair market value of the common stock on the date of the grant which is approved by the board of directors of the Company. The Stock Incentive Plan had 5,000,000 shares of common stock reserved for grant at December 31, 2012. In February 2013, the Company amended the Stock Incentive Plan to increase the shares of common stock reserved for grant to 8,500,000. In September 2015, the Company amended the Stock Incentive Plan to increase the shares of common stock reserved for grant to 12,500,000.

The terms of the options granted under the Stock Incentive Plan expire as determined by individual option agreements (or on the tenth anniversary of the grant date), unless terminated earlier on the first to occur of the following: (1) the date on which the participant's service with the Company is terminated by the Company for cause; (2) 60 days after the participant's death; or (3) 60 days after the termination of the participant's service with the Company for any reason other than cause or the participant's death; provided that, if during any part of such 60 day period the option is not exercisable solely because of specified securities law restrictions, the option will not expire until the earlier of the expiration date or until it has been exercisable for an aggregate period of 60 days after the termination of the participant's service with the Company. The options vest as provided for in each individual's option agreement and the exercise prices for the options are determined by the board of directors at the time the option is granted; provided that the exercise price shall in no event be less than the fair market value per share of the Company's Common Stock on the grant date. In the event of any change in the Common Stock underlying the options, by reason of any merger or exchange of shares of common stock, the board of directors shall make such substitution or adjustment as it deems to be equitable to (1) the class and number of shares underlying such option, (2) the exercise price applicable to such option, or (3) any other affected terms of such option.

In the event of a change of control, unless specifically modified by an individual option agreement: (1) all options outstanding as of the date of such change of control will become fully vested; and (2) notwithstanding (1) above, in the event of a merger or share exchange, the board of directors may, in its sole discretion, determine that any or all options granted pursuant to the Stock Incentive Plan will not vest on an accelerated basis if the board of directors, the surviving corporation or the acquiring corporation, as the case may be, has taken such action as in the opinion of the board of directors is equitable or appropriate to protect the rights and interests of the participants under the Stock Incentive Plan.

On December 31, 2014, there were 2,335,522 shares of Common Stock available for grant under the Stock Incentive Plan. For the years ended December 31, 2014 and 2013, there were 50,000 and 3,072,759 options granted to the Company's executive officers under the Stock Incentive Plan, respectively.

Outstanding Equity Awards at 2015 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2015.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options/	Number of Securities Underlying Unexercised Options/	Equity Incentive Plan Awards: Number	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units	Market Value of Shares or	Equity Incentive Plan Awards: Number	Equity Incentive Plan Awards: Market

	Warrants (#) Exercisable	Warrants (#) Unexercisable	of Securities Underlying Unexercised Unearned Options (#)			of Stock That Have Not Vested (#)	Units of Stock That Have Not Vested ($)	of Unearned Shares, Units or Other Rights That Have Not Vested (#)	or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II Chairman of the Board and Co-Chief Executive Officer (principal executive officer)	115,000[1]	-	-	$ 0.35	02/21/2023	-	-	-	-
	452,381[3]	-	-	$ 0.11	10/1/2025	-	-	-	-
	297,619[3]	-	-	$ 0.50	10/1/2025	-	-	-	-
Lisa Sundstrom Chief Finanical Officer (principal executive officer)	65,000[1]	-	-	$ 0.35	02/21/2023	-	-	-	-
	16,666[2]	8,334[2]	-	$ 0.55	5/7/2024	-	-	-	-
	301,587[3]	-	-	$ 0.11	10/1/2025	-	-	-	-
	198,413[3]	-	-	$ 0.50	10/1/2025	-	-	-	-
Barry J. Jenkins [4] (Chief Financial Officer and COO)	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-

(1) On February 21, 2013, the Company, by mutual agreement with all active employees and directors of the Company, cancelled options granted to the active employees and directors in the year ended December 31, 2011 and prior. In exchange for these
options, the active employees and directors received new options to purchase shares of common stock at an exercise price of $0.35 per share. The Company cancelled 15,000 options which were previously granted to Mr. Richardson. The Company
granted Mr. Richardson 115,000 options on February 21, 2013 which vests one-third at grant date, one-third on February 21, 2014 and one-third on February 21, 2015.
(2) The Company granted Ms. Sundstrom 25,000 options on May 7, 2014 which vests one-third at grant date, one-third on May 7, 2015 and one-third on May 7, 2016.
(3) The Company granted Mr. Richardson 750,000 options and Ms. Sundstrom 500,000 options on October 1, 2015 which vests at grant date.
(4) Mr. Jenkins terminated his employment with the company on July 31, 2015 and forfeited all of his options.

Director Compensation Table for Fiscal 2015

The following table provides certain information concerning compensation for each director during the fiscal year ended December 31, 2015.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Kevin A. Richardson, II [(1)]	$16,000	-	$79,524	-	-	-	$99,524
John F. Nemelka	$16,000	-	$26,508	-	-	-	$46,508
Alan L. Rubino	$16,000	-	$26,508	-	-	-	$46,508

(1) Mr. Richardson has been the Company's Chairman of the Board since the Company's inception. In April 2014, Mr. Richardson assumed the role of Co-Chief Executive Officer and was paid $10,000 per month thereafter for his performance of that role.

The following are the aggregate number of option awards outstanding that have been granted to each of our non-employee directors as of December 31, 2015: Kevin A. Richardson, II – 750,000, John F. Nemelka – 250,000 and Alan L. Rubino – 250,000.

Discussion of Director Compensation

Effective January 1, 2013, the Company began to compensate its three non-employee directors at an annual rate of $16,000 each. On October 1, 2015, the Company issued 150,795 options to purchase the Company's Common Stock at $0.11 per share and 99,205 options to purchase the Company's Common Stock at $0.50 per share to non-employee directors John F. Nemelka and Alan L. Rubino. On October 1, 2015, the Company issued 452,381 options to purchase the Company's Common Stock at $0.11 per share and 297,619 options to purchase the Company's Common Stock at $0.50 per share to non-employee director Kevin A. Richardson, II.

Committee Interlocks and Insider Participation

The Compensation Committee is comprised of Kevin A. Richardson, II, John F. Nemelka and Alan L. Rubino. Both Mr. Richardson and Mr. Nemelka have had certain relationships and related party transactions described further in the section entitled “Certain Relationships and Related Transactions—Related Party Transactions.” During 2015, none of our executive officers served as a director or member of a compensation committee (or other committee serving an equivalent function) of any other entity whose executive officers served as a director or member of the Compensation Committee.

CORPORATE GOVERNANCE AND BOARD MATTERS

The Company adopted a formal Corporate Governance policy in January 2012 which included establishing formal board committees and a code of conduct for the board of directors and the Company.

The Board of Directors

Board’s Leadership Structure

The Company’s board of directors elects the Company’s chief executive officer and its chairman, and each of these positions may be held by the same person or may be held by two persons. Although the Company’s board of directors believes that it is in the best interest of the Company and its shareholders to separate the roles of chairman of the board and chief executive officer, Mr. Richardson is currently performing each of these roles until the Company completes its search for a new chief executive officer.

The chairman’s primary responsibilities are to manage the board and serve as the primary liaison between the board of directors and the chief executive officer, while the primary responsibility of the chief executive officer is to manage the day-to-day affairs of the Company, taking into account the policies and directions of the board of directors. Such an arrangement promotes more open and robust communication among the board, and provides an efficient decision making process with proper independent oversight. With the resignation of Christopher M. Cashman as President and Chief Executive Officer, and a director of the Company, effective November 7, 2012, the board of directors elected Kevin A. Richardson, the Chairman of the board, to also assume the function of Acting Chief Executive Officer until Joseph Chiarelli joined the Company in February 2013 as Chief Executive Officer and a director. Mr. Richardson

remained Chairman of the board. Mr. Richardson assumed the role of Co-Chief Executive Officer of the Company on April 14, 2014. Mr. Chiarelli left the role of Co-Chief Executive Officer as of April 15, 2014 and resigned as a director of the Company on July 31, 2014. Since that time Mr. Richardson has reassumed the role of Acting Chief Executive Officer.

The Company believes that there is no single leadership structure that is the best and most effective in all circumstances and at all times. Accordingly, the board of directors retains the authority to later combine these roles permanently if doing so would be in the best interests of the Company and its shareholders.

The Company's board of directors is authorized to have an audit committee, a compensation committee and a nominating and corporate governance committee, to assist the Company's board of directors in discharging its responsibilities. The Company's current board of directors consists of three (3) members, only one of whom has been determined by the board to be "independent" as defined under the rules of the NASDAQ stock market. The Company added one independent director to the board of directors in 2013 and had one director resign on July 31, 2014. The board of directors has determined that Mr. Richardson and Mr. Nemelka are not independent under the applicable marketplace rules of the NASDAQ stock market and Rule 10A-3 under the Exchange Act. The Company expects to add additional independent directors in 2016.

Board's Role in Risk Oversight

While the Company's management is responsible for the day-to-day management of risk to the Company, the board of directors has broad oversight responsibility for the Company's risk management programs. The various committees of the board of directors assist the board of directors in fulfilling its oversight responsibilities in certain areas of risk. In particular, the audit committee focuses on financial and enterprise risk exposures, including internal controls, and discusses with management and the Company's independent registered public accountants the Company's policies with respect to risk assessment and risk management. The compensation committee is responsible for considering those risks that may be implicated by the Company's compensation programs and reviews those risks with the Company's board of directors and chief executive officer.

Audit Committee

The current members of the Company's audit committee are Kevin A. Richardson, II, John F. Nemelka and Alan L. Rubino. Mr. Richardson, who chairs the committee, has been determined by the board of directors to be an audit committee financial expert as defined pursuant to the rules of the SEC. Pursuant to the Company's Audit Committee Charter, the audit committee is required to consist of at least two independent directors. The Company currently only has one independent director. The Company expects to add additional independent directors to the board of directors in 2016.

The audit committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com*. The primary responsibility of the audit committee is to oversee the Company's financial reporting process on behalf of the board of directors. Among other things, the audit committee is responsible for overseeing the Company's accounting and financial reporting processes and audits of the Company's financial statements, reviewing and discussing with the independent auditors the critical accounting policies and practices for the Company, engaging in discussions with management and the independent auditors to assess risk for the Company and management thereof, and reviewing with management the effectiveness of the Company's internal controls and disclosure controls and procedures. The audit committee is directly responsible for the appointment, compensation, retention and oversight of the work of the Company's independent auditors, currently BDO USA, LLP, including the resolution of disagreements, if any, between management and the auditors regarding financial reporting. In addition, the audit committee is responsible for reviewing and approving any related party transaction that is required to be disclosed pursuant to Item 404 of Regulation S-K promulgated under the Exchange Act.

Compensation Committee

The current members of the Company's compensation committee are Kevin A. Richardson, II, John F. Nemelka and Alan L. Rubino. The primary purpose of the compensation committee is to discharge the responsibilities of the board of directors relating to compensation of the Company's executive officers. Pursuant to the Company's Compensation Committee Charter, the compensation committee is required to consist of at least two independent directors. The Company currently only has one independent director. The Company expects to add additional independent directors to the board of directors in 2016.

The compensation committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com*. Specific responsibilities of the compensation committee include reviewing and recommending approval of compensation of the Company's named executive officers, administering the Company's stock incentive plan, and reviewing and making recommendations to the Company's board of directors with respect to incentive compensation and equity plans.

Nominating and Corporate Governance Committee

The current members of the Company's nominating and corporate governance committee are Kevin A. Richardson, II, John F. Nemelka and Alan L. Rubino. Pursuant to the Company's Nominating and Corporate Governance Committee Charter, the nominating and corporate governance committee is required to consist of at least two independent directors. The Company currently only has one independent director. The Company expects to add additional independent directors to the board of directors in 2016.

The nominating and corporate governance committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com.* Specific responsibilities of the nominating and corporate governance committee include: identifying and recommending nominees for election to the Company's board of directors; developing and recommending to the board of directors the Company's corporate governance principles; overseeing the evaluation of the board of directors; and reviewing and approving compensation for non-employee members of the board of directors.

The nominating and corporate governance committee's charter outlines how the nominating and corporate governance committee fulfills its responsibilities for assessing the qualifications and effectiveness of the current board members, assessing the needs for future board members, identifying individuals qualified to become members of the board and its committees, and recommending candidates for the board of director's selection as director nominees for election at the next annual or other properly convened meeting of shareholders.

The nominating and corporate governance committee considers director candidates recommended by shareholders for nomination for election to the board of directors. The committee applies the same standards in considering director candidates recommended by the shareholders as it applies to other candidates. Any shareholder entitled to vote for the election of directors may recommend a person or persons for consideration by the committee for nomination for election to the board of directors. The Company must receive written notice of such shareholder's recommended nominees(s) no later than January 31st of the year in which the shareholder wishes such recommendation to be considered by the committee in connection with the next meeting of shareholders at which the election of directors will be held. To submit a recommendation, a shareholder must give timely notice thereof in writing to the Secretary of the Company. A shareholder's notice to the Secretary shall set forth: (i) the name and record address of the shareholder making such recommendation and any other shareholders known by such shareholder to be supporting such recommendation; (ii) the class and number of shares of the Company which are beneficially owned by the shareholder and by any other shareholders known by such shareholder to be supporting such recommendation; (iii) the name, age and five year employment history of such recommended nominee; (iv) the reasons why the shareholder believes the recommended nominee meets the qualifications to serve as a director of the Company; and (v) any material or financial interest of the shareholder and, if known, the recommended nominee in the Company.

Shareholder Communications with the Board of Directors

The board of directors has implemented a process for shareholders to send communications to the board of directors. Shareholders who wish to communicate directly with the board of directors or any particular director should deliver any such communications in writing to the Secretary of the Company. The Secretary will compile any communications he receives from shareholders and deliver them periodically to the board of directors or the specific directors requested. The Secretary of the Company will not screen or edit such communications, but will deliver them in the form received from the shareholder.

Code of Conduct and Ethics

It is the Company's policy to conduct its affairs in accordance with all applicable laws, rules and regulations of the jurisdictions in which it does business. The Company has adopted a code of business conduct and ethics with policies and procedures that apply to all associates (all employees are encompassed by this term, including associates who are officers) and directors, including the chief executive officer, chief financial officer, controller, and persons performing similar functions.

The Company has made the code of business conduct and ethics available on its website at *www.sanuwave.com.* If any substantive amendments to the code of business conduct and ethics are made or any waivers are granted, including any implicit waiver, the Company will disclose the nature of such amendment or waiver on its website or in a Current Report on Form 8-K.

No Family Relationships Among Directors and Officers

There are no family relationships between any director or executive officer of the Company and any other director or executive officer of the Company.

Director Independence

Our board of directors has determined that Alan L. Rubino qualifies as an independent director based on the NASDAQ Stock Market definition of "independent director."

Limitation of Directors Liability and Indemnification

The Nevada Revised Statutes authorize corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Nevada law.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act of 1933, as amended. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is one of our officers or directors, is involved in a legal proceeding of any nature.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of our equity securities which are registered pursuant to Section 12 of the Exchange Act, to file with the SEC initial reports of ownership and reports of changes in ownership of our equity securities. Officers, directors and greater than 10% shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of the Forms 3, 4 and 5 (and amendments thereto) furnished to us for our fiscal year ended December 31, 2015, we have determined that our directors, officers and greater than 10% beneficial owners complied with all applicable Section 16 filing requirements.

Disclosure of Commission Position on Indemnification of Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information, as of February 12, 2016, with respect to the beneficial ownership of the Company's outstanding Common Stock by (i) any holder of more than five percent (5.0%), (ii) each of the Company's executive officers and directors, and (iii) the Company's directors and executive officers as a group.

Name of Beneficial Owner [1]	**Number of Shares Beneficially Owned** [2]	**Percent of Shares Outstanding**
Kevin A. Richardson, II [3]	8,902,588	12.6%
John F. Nemelka [4]	382,248	0.6%
Alan Rubino [5]	350,000	0.5%
All directors and executive officers as a group (3 persons)	9,634,835	13.7%
5% Beneficial Owner:		
Prides Capital Fund I, LP [6]	5,514,081	7.8%
RA Capital Healthcare Fund, L.P. [7]	9,956,624	14.1%

(1) Unless otherwise noted, each beneficial owner has the same address as us.

(2) Applicable percentage ownership is based on 70,504,473 shares of common stock outstanding as of January 15, 2016, "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of January 15, 2016. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.

(3) Includes options to purchase up to 865,000 shares of common stock and warrants to purchase up to 218,947 shares of common stock. In addition, this amount includes 5,805,371 shares of common stock and warrants to purchase 662,362 shares of common stock owned directly by Prides Capital Fund I, L.P. Prides Capital Partners LLC is the general partner of Prides Capital Fund I, L.P. and Mr. Richardson is the controlling shareholder of Prides Capital Partners LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. Richardson has also been deputized by Prides Capital Partners LLC to serve on the board of directors of the Company. Mr. Richardson disclaims beneficial ownership of all such securities except to the extent of any indirect pecuniary interest (within the meaning of Rule 16a-1 of the Exchange Act) therein.

(4) Includes options to purchase up to 365,000 shares of common stock. In addition, this amount includes warrants to purchase 16,702 shares of common stock owned directly by NightWatch Capital Partners II, L.P. NightWatch Capital

Management, LLC, is the general partner of NightWatch Capital Partners II, L.P. and Mr. John Nemelka is the controlling shareholder of NightWatch Capital Management LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. John Nemelka has also been deputized by NightWatch Capital Management LLC to serve on the board of directors of the Company. Mr. John Nemelka disclaims beneficial ownership of all such securities except to the extent of any indirect pecuniary interest (within the meaning of Rule 16a-1 of the Exchange Act) therein.

(5) Consists of options to purchase up to 350,000 shares of common stock.

(6) Based on the records of the Company, includes warrants to purchase 662,362 shares of common stock. The principal business address of Prides Capital Fund I, LP is 100 Cummings Center, Suite 324C, Beverly, MA 01915. Kevin A. Richardson, II has voting and dispositive power over the securities. See footnote (2).

(7) Shares reported herein for RA Capital Healthcare Fund, L.P. represent 5,291,451 shares of common stock issued upon the conversion of Series A Warrants held of record by the fund. Shares reported herein for RA Capital Management, LLC represent (a) the above-referenced shares of common stock issuable upon the conversion of certain warrants as reported for RA Capital Healthcare Fund, L.P. for which RA Capital Management, LLC serves as the sole general partner, (b) 3,072,114 shares of common stock equivalents from Series B Convertible Preferred Stock, (c) 1,007,895 shares of shares of common stock issued upon the conversion of Series A Warrants and (d) 585,164 shares of common stock equivalents from Series B Convertible Preferred Stock held in a separately managed account for Blackwell Partners, LLC for which RA Capital Management, LLC serves as investment adviser. Each of the Reporting Persons disclaims beneficial ownership of the shares reported herein except to the extent of its or his pecuniary interest therein. The principal business office of the Reporting Persons is c/o RA Capital Management, LLC, 20 Park Plaza, Suite 1200, Boston, MA 02116.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Party Transactions

Other than as described below, since January 1, 2012, there have been no transactions, and there are no currently proposed transactions with related persons required to be disclosed in this prospectus.

On August 13, 2015, the Company entered into a Settlement Agreement and Mutual Releases (the "*Settlement Agreement*") with Joseph Chiarelli, the Company's former Chief Executive Officer. Entry into the Settlement Agreement was made in connection with Mr. Chiarelli's resignation as Chief Executive Officer, and a director of the Company, in 2015. See "Management, Executive Compensation and Corporate Governance – Joseph Chiarelli – Settlement Agreement."

On March 17, 2014, in conjunction with a private placement of securities (previously defined as the "*2014 Private Placement*") with institutional and select accredited investors, the Company issued an aggregate total of 6,210,000 shares of common stock and 6,175 shares of preferred stock (the "*Series A Convertible Preferred Stock*") for an aggregate total purchase price of $9,280,000. Each share of Series A Convertible Preferred Stock is convertible into 2,000 shares of Common Stock at the option of the holder. The proceeds received by the Company were $8,562,500, net of offering costs of $717,500. The Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 23,200,000 warrants (the "*Series A Warrants*") to purchase shares of Common Stock at an exercise price of $0.50 per share. Each Series A Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after five years. In addition, the Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 13,920,000 warrants (the "*Series B Warrants*") to purchase shares of Common Stock at an exercise price of $1.50 per share. Each Series B Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after one year. Kevin A. Richardson, II, chairman of the board of directors of the Company and Co-Chief Executive Officer; Joseph Chiarelli, the former Chief Executive Officer and director of the Company; and, Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, were purchasers in the 2014 Private Placement of $50,000, $40,000 and $50,000, respectively.

During the period January 24, 2014 through March 7, 2014, the Company entered into subscriptions payable for 18% convertible promissory notes, as amended, (previously defined as the "*18% Convertible Promissory Notes*") from selected accredited investors. Up to $1,000,000 aggregate principal amount of 18% Convertible Promissory Notes were offered by the Company. The Company completed the offering and issued an aggregate $815,000 in convertible notes in March 2014. Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, purchased $110,000 of the convertible notes.

In September, October and December 2013, the Company, in conjunction with offerings of securities (as previously defined as the "*Private Placements*") of the Company, pursuant to an exemption from registration under the Act, issued 1,043,646 units (as described below) to certain "accredited investors," as that term is defined in SEC Rule 501 under the Act, for an aggregate total purchase price of $626,188. Each unit was sold to the accredited investors at a purchase price of $0.60 per unit. Each unit in the Private Placements consists of; (i) one share of Common Stock and (ii) a five-year warrant to purchase one share of Common Stock, at an exercise price of $0.85. Kevin A. Richardson II, who is the chairman of the board of directors of the Company, and Joseph Chiarelli, who is the Chief Executive Officer of the Company, and Michael M. Nemelka, who is the brother of John F. Nemelka, a member of the board of directors of the Company, purchased units in the Private Placements.

The Company issued short-term, unsecured promissory notes, in the aggregate principal amount of $360,000, between May 14, 2013 and July 9, 2013, to certain existing shareholders. The promissory notes accrue interest at a rate of 18% per annum and, together with all accrued and unpaid interest, are due and payable 179 days from their individual issuance date. In the event that the promissory notes are not paid in full within three business days of their respective maturity dates, then, from and after such maturity date and until payment in full, interest will accrue on the outstanding principal balance at a rate of 25% per annum. Joseph Chiarelli, the Company's Chief Executive Officer, purchased promissory notes in the offering in the principal amount of $35,000. David N. Nemelka, the brother of John F. Nemelka, who is a member of the Company's board of directors, purchased promissory notes in the offering in the principal amount of $100,000. On August 1, 2013, at the request of the promissory note holders, the Company repaid $325,000 of the original principal value of the notes in full, along with accrued interest of $10,664. At December 31, 2013, there was one promissory note outstanding for $38,038, including accrued interest, payable to Joseph Chiarelli.

During the period from November 2012 through March 8, 2013, the Company entered subscriptions payable for 18% senior secured convertible promissory notes (as previously defined as the "*Senior Secured Notes*") from select accredited investors. The Company completed the offering and issued an aggregate $2,000,000 in Senior Secured Notes on March 8, 2013. On July 31, 2013, all of the holders of the Senior Secured Notes voluntarily converted all of the outstanding principal and interest of the Senior Secured Notes into Company Common Stock. The aggregate outstanding amount of principal and interest on the Senior Secured Notes at July 31, 2013 of $2,186,906 was converted into 10,934,533 shares of restricted Company Common Stock at the conversion price of $0.20 per share - the market price at the time the subscription agreement was written - pursuant to the Senior Secured Note agreements. In return for the Holders voluntarily converting the outstanding Senior Secured Notes on or before July 31, 2013, the Company agreed to issue to the Holders warrants to purchase an aggregate total of 1,988,095 shares of Common Stock. The warrants have an exercise price of $0.80 per share and are exercisable during the five-year period beginning on the date of issuance. Kevin A. Richardson, II, chairman of the board of directors of the Company, converted an aggregate balance of $64,500 of the Senior Secured Notes and received 322,500 shares of common stock and 58,635 warrants in the foregoing transaction.

On November 27, 2012, the Company and David N. Nemelka (the "*Subscriber*"), the brother of John F. Nemelka, a member of the Company's board of directors, entered into a subscription agreement (the "*Subscription Agreement*") whereby the Subscriber has agreed to purchase from the Company, and the Company has agreed to sell and issue, a total of 4,000,000 shares of the Company's unregistered Common Stock at a purchase price equal to $0.25 per share, for an aggregate sales price of $1,000,000 (the "*Purchase Price*"). The Purchase Price shall be payable to the Company as follows: (i) $50,000 on or before January 31, 2013; (ii) $50,000 on or before February 15, 2013; and (iii) the balance of $900,000 on or before May 27, 2014 (the "*Outside Due Date*"). As of December 31, 2012, the Subscriber had paid the Company $25,000 and was issued 100,000 shares of unregistered common stock of the Company. During the year ended December 31, 2013, the Subscriber paid the Company an additional $75,000 and was issued an additional 300,000 shares of unregistered common stock of the Company. The Subscriber completed its obligations under the Subscription Agreement with the additional $900,000 being received on May 27, 2014, and the Company issued the corresponding 3,600,000 shares of Common Stock.

On November 6, 2012, the Company entered into a Severance and Advisory Agreement (the "*Severance Agreement*") with Christopher M. Cashman, then a director of the Company, and the Company's President and Chief Executive

Officer. Entry into the Severance Agreement was made in connection with Mr. Cashman's resignation as President and Chief Executive Officer, and a director of the Company, effective November 7, 2012.

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 355,000,000 shares, of which 350,000,000 shares are designated as Common Stock and 5,000,000 shares are designated as preferred stock. As of February 12, 2016, there were issued and outstanding:

70,504,473 shares of Common Stock,

warrants to purchase 14,601,258 shares of Common Stock at a weighted average exercise price of $1.46 per share, and

stock options to purchase 8,573,385 shares of Common Stock at a weighted average exercise price of $0.64 per share.

The following summary of the material provisions of our Common Stock, preferred stock and warrants is qualified by reference to the provisions of our articles of incorporation and bylaws and the forms of warrant included or incorporated by reference as exhibits to the registration statement of which this prospectus is a part.

Common Stock

All shares of our Common Stock have equal voting rights and, when validly issued and outstanding, have one vote per share in all matters to be voted upon by the stockholders. Cumulative voting in the election of directors is not allowed, which means that the holders of more than 50% of the outstanding shares can elect all the directors if they choose to do so and, in such event, the holders of the remaining shares will not be able to elect any directors. The affirmative vote of a plurality of the shares of Common Stock voted at a stockholders meeting where a quorum is present is required to elect directors and to take other corporate actions. Holders of our Common Stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds. However, the current policy of our board of directors is to retain earnings, if any, for the operation and expansion of the Company. Upon liquidation, dissolution or winding-up, the holders of our Common Stock are entitled to share ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities and the liquidation preference of any outstanding preferred stock. The holders of our Common Stock have no preemptive, subscription, redemption or conversion rights. All issued and outstanding shares of Common Stock are, and the Common Stock reserved for issuance upon exercise of our stock options and warrants will be, when issued, fully-paid and non-assessable.

Preferred Stock

Our articles of incorporation authorize the issuance of up to 5,000,000 shares of “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by our board of directors. As of February 12, 2016 there are 293 shares of Series B preferred shares outstanding.

Warrants

The following is a brief summary of material provisions of the warrants offered in this offering.

Exercise Price and Terms. Each warrant entitles the holder thereof to purchase at any time until March 17, 2019, at a price of $0.08 per share, subject to certain adjustments referred to below, shares of our Common Stock. The holder of any warrant may exercise such warrant by surrendering the warrant to us, with the notice of exercise properly completed and executed, together with payment of the exercise price. The warrants may be exercised at any time in whole or in part at the applicable exercise price until expiration of the warrants. No fractional shares will be issued upon the exercise of the warrants.

Adjustments. The exercise price and the number of shares of Common Stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of certain events, including stock dividends, stock splits, combinations or reclassifications of the Common Stock. Additionally, an adjustment would be made in the case of a reclassification or exchange of Common Stock, consolidation or merger of our Company with or into another corporation (other than a consolidation or merger in which we are the surviving corporation) or sale of all or substantially all of our assets in order to enable holders of the warrants to acquire the kind and number of shares of stock or other securities or property receivable in such event by a holder of the number of shares of Common Stock that might otherwise have been purchased upon the exercise of the warrant. No adjustment to the number of shares and exercise price of the shares subject to the warrants will be made for dividends (other than stock dividends), if any, paid on our Common Stock.

Transfer, Exchange and Exercise. The warrants may be presented to us for exchange or exercise at any time on or prior to March 17, 2019, at which time the warrants become wholly void and of no value. Prior to any transfer of the warrants the holder must notify us of the same and, if subsequently requested, provide a legal opinion regarding the transfer to us.

Warrantholder Not a Stockholder. The warrants do not confer upon holders any voting, dividend or other rights as a shareholder of our Company.

Trading Information

Our shares of Common Stock are currently quoted in the over-the-counter market on the OTC Bulletin Board under the symbol “SNWV.OB”.

Transfer Agent

The transfer agent and registrar for our Common Stock and preferred stock is Action Stock Transfer Corp., 7069 S. Highland Drive, Suite 300, Salt Lake City, Utah 84121

SHARES AVAILABLE FOR FUTURE SALE

As of February 12, 2016, we had 70,504,473 shares of Common Stock outstanding, not including shares issuable upon the exercise of outstanding warrants, stock options and other convertible securities. All shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless they are purchased by our "affiliates," as that term is defined in Rule 144 promulgated under the Securities Act.

The outstanding shares of our Common Stock not included in this prospectus will be available for sale in the public market as follows:

Public Float

Of our outstanding shares, 7,156,825 shares are beneficially owned by executive officers, directors and affiliates of the Company. The remaining 63,347,648 shares constitute our public float which, based on the last sale price of our Common Stock reported on the OTC Bulletin Board on February 12, 2016, equaled approximately $4,434,335.

Rule 144

In general, under Rule 144, as currently in effect, a person who has beneficially owned shares of our Common Stock for at least six (6) months, including the holding period of prior owners other than affiliates, is entitled to sell his or her shares without any volume limitations; an affiliate, however, can sell such number of shares within any three-month period as does not exceed the greater of:

1% of the number of shares of our Common Stock then outstanding, which equaled 705,045 shares as of February 12, 2016, or

the average weekly trading volume of our Common Stock, assuming our shares are then traded on a national securities exchange, during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 are also subject to manner-of-sale provisions, notice requirements and the availability of current public information about us.

LEGAL MATTERS

Certain legal matters will be passed upon for us by Smith, Gambrell & Russell, LLP, Atlanta, Georgia.

EXPERTS

The consolidated financial statements as of December 31, 2014 and 2013 and for the years then ended included in this prospectus and in the registration statement have been so included in reliance on the reports of BDO USA, LLP (an independent registered public accounting firm, the report on the financial statements contains an explanatory paragraph regarding the Company’s ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

INTEREST OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the Common Stock was employed on a contingency basis, or had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC to register the shares of our Common Stock being offered by this prospectus. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any reports, statements or other information that we file at the SEC's public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information regarding the public reference facilities. The SEC maintains a website, *http://www.sec.gov* that contains reports, proxy statements and information statements and other information regarding registrants that file electronically with the SEC, including us. Our SEC filings are also available to the public from commercial document retrieval services. Information contained on our website should not be considered part of this prospectus.

You may also request a copy of our filings at no cost by writing or telephoning us at:

SANUWAVE Health, Inc.

11475 Great Oaks Way, Suite 150

Alpharetta, Georgia 30022

Attn: Lisa Sundstrom, Chief Financial Officer

Telephone: (770) 419-7525

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

SANUWAVE Health, Inc. and Subsidiaries

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	September 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$625,450	$3,547,071
Accounts receivable, net of allowance for doubtful accountsof $5,832 in 2015 and $15,018 in 2014	32,008	86,404
Inventory	291,354	271,871
Prepaid expenses	152,261	128,550
TOTAL CURRENT ASSETS	1,101,073	4,033,896
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4)	5,065	7,840
OTHER ASSETS	11,160	11,106
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 5)	383,445	613,513
TOTAL ASSETS	$1,500,743	$4,666,355
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$315,651	$231,840
Accrued expenses (Note 6)	400,488	369,456
Accrued employee compensation	200,807	2,226
Interest payable, related parties (Note 7)	100,123	81,864
Notes payable, related parties (Note 7)	-	5,372,743
Warrant liability (Note 11)	267,600	159,626
TOTAL CURRENT LIABILITIES	1,284,669	6,217,755
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 7)	5,342,412	-
TOTAL LIABILITIES	6,627,081	6,217,755
COMMITMENTS AND CONTINGENCIES (Note 12)		

STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001,6,175 authorized; 6,175 shares issued and 0 and 1,165 shares outstanding in 2015 and 2014, respectively (Note 10)	-	1
PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,825 shares authorized; no shares issued and outstanding (Note 10)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 63,056,519 and 60,726,519 issued and outstanding in 2015 and 2014, respectively (Note 9)	63,057	60,727
ADDITIONAL PAID-IN CAPITAL	86,728,528	86,584,472
ACCUMULATED DEFICIT	(91,891,615)	(88,184,123)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(26,308)	(12,477)
TOTAL STOCKHOLDERS' DEFICIT	(5,126,338)	(1,551,400)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,500,743	$4,666,355

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
REVENUES	$143,605	$227,492	$594,040	$610,705
COST OF REVENUES	38,752	68,077	173,349	149,813
GROSS PROFIT	104,853	159,415	420,691	460,892
OPERATING EXPENSES				
Research and development	569,134	708,304	1,660,546	2,486,801
General and administrative	778,679	780,115	1,981,541	2,774,828
Depreciation	926	3,827	2,775	13,312
Amortization	76,689	76,689	230,068	230,067
TOTAL OPERATING EXPENSES	1,425,428	1,568,935	3,874,930	5,505,008
OPERATING LOSS	(1,320,575)	(1,409,520)	(3,454,239)	(5,044,116)
OTHER INCOME (EXPENSE)				
Gain on sale of assets held for sale	100,000	-	100,000	-
Gain (loss) on warrant valuation adjustment (Note 12)	302,300	-	(70,985)	-
Interest expense, net	(105,830)	(79,955)	(266,810)	(700,085)
Loss on foreign currency exchange	(2,739)	(3,430)	(15,458)	(6,308)
TOTAL OTHER INCOME (EXPENSE)	293,731	(83,385)	(253,253)	(706,393)
NET LOSS	(1,026,844)	(1,492,905)	(3,707,492)	(5,750,509)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	(345)	(10,210)	(13,831)	(15,191)
TOTAL COMPREHENSIVE LOSS	$(1,027,189)	$(1,503,115)	$(3,721,323)	$(5,765,700)
LOSS PER SHARE:				
Net loss - basic and diluted	$(0.02)	$(0.03)	$(0.06)	$(0.12)
Weighted average shares outstanding - basic and diluted	63,056,519	50,706,519	63,014,763	46,258,912

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(3,707,492)	$(5,750,509)
Adjustments to reconcile loss from continuing operationsto net cash used by operating activities		
Amortization	230,068	230,067
Depreciation	2,775	13,312
Change in allowance for doubtful accounts	(9,186)	4,762
Stock-based compensation - employees, directors and advisors	146,385	91,788
Loss on warrant valuation adjustment	70,985	-
Amortization of debt discount	6,658	-
Gain on sale of property and equipment	(100,000)	
Stock issued for consulting services	-	743,150
Accretion of interest on warrants issued concurrent with a convertible promissory note	-	339,864
Accrued interest on 18% Convertible Promissory Notes	-	7,168
Changes in assets - (increase)/decrease		
Accounts receivable - trade	63,582	40,020
Inventory	(19,483)	(11,956)
Prepaid expenses	(23,711)	(87,286)
Other	(54)	216
Changes in liabilities - increase/(decrease)		
Accounts payable	83,811	(532,354)
Accrued expenses	31,032	(504,354)
Accrued employee compensation	198,581	(22,402)
Interest payable, related parties	18,259	(81,865)
Promissory notes - accrued interest	-	(21,813)
NET CASH USED BY OPERATING ACTIVITIES	(3,007,790)	(5,542,192)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of property and equipment	100,000	-
Purchase of property and equipment	-	(8,859)
NET CASH PROVIDED BY (USED BY) INVESTING ACTIVITIES	100,000	(8,859)

CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from 2014 Private Placement, net	-	8,562,500
Proceeds from sale of capital stock - subscription agreement	-	900,000
Proceeds from 18% Convertible Promissory Notes	-	815,000
Proceeds from convertible promissory notes, net	-	325,000
Proceeds from employee stock option exercise	-	12,600
Payments of principal on convertible promissory notes	-	(450,000)
Payments of principal on promissory notes	-	(90,000)
Payments of principal on capital lease	-	(3,951)
NET CASH PROVIDED BY FINANCING ACTIVITIES	-	10,071,149
EFFECT OF EXCHANGE RATES ON CASH	(13,831)	(15,191)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,921,621)	4,504,907
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,547,071	182,315
CASH AND CASH EQUIVALENTS, END OF PERIOD	$625,450	$4,687,222
SUPPLEMENTAL INFORMATION		
Cash paid for interest	$242,904	$325,804

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

1. Nature of the Business

SANUWAVE Health, Inc. and subsidiaries (the "Company") is a shockwave technology company using a patented system of noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. The Company's 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. The Company's lead regenerative product in the United States is the dermaPACE® device, which is in a supplemental Phase III clinical study for treating diabetic foot ulcers.

The Company's 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. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. Revenues are from sales of the European Conformity Marking ("CE Mark") devices and accessories in Europe, Canada, Asia and Asia/Pacific.

In addition, there are license/partnership opportunities for the Company's shockwave technology for non-medical uses, including energy, water, food and industrial markets.

2. Going Concern

The continuation of the Company's business is dependent upon raising additional capital before the conclusion of fourth quarter of 2015. As of September 30, 2015, the Company had an accumulated deficit of $91,891,615 and cash and cash equivalents of $625,450. For the nine months ended September 30, 2015 and 2014, the net cash used by operating activities was $3,007,790 and $5,542,192, respectively. The Company incurred a net loss of $3,707,492 for the nine months ended September 30, 2015 and a net loss of $5,974,080 for the year ended December 31, 2014. The operating losses create an uncertainty about the Company's ability to continue as a going concern.

The continuation of the Company's business is dependent upon raising additional capital before the conclusion of fourth quarter of 2015 to fund operations. Management's plans are to obtain additional capital through the issuance of

common or preferred stock, securities convertible into common stock or secured or unsecured debt, investments by strategic partner for market opportunities, which may include strategic partnerships or licensing arrangements or complete a joint venture, partnership or sale of the wound product to complete the FDA trial successfully and begin commercialization of the product in 2016. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. The condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and footnotes required by United States generally accepted accounting principles for complete financial statements. The financial information as of September 30, 2015 and for the three and nine months ended September 30, 2015 and 2014 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2015 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2015.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

3. Summary of Significant Accounting Policies (continued)

The condensed consolidated balance sheet at December 31, 2014 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements.

Significant Accounting Policies

For further information and a summary of significant accounting policies, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 3, 2015.

Recently Issued Accounting Standards

New accounting pronouncements are issued by the Financial Standards Board ("FASB") or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies. The Company does not expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company's results of operations, financial position or cash flow.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional

footnote disclosures). In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2019 instead of the current effective date, which was the first quarter of fiscal 2018. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606)*, deferring the effective date of ASU 2014-09 by one year. The Company can elect to adopt the provisions of ASU 2014-09 for annual periods beginning after December 31, 2017, including interim periods within that reporting period. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on the consolidated financial statements and has not yet determined the method by which the Company will adopt the standard.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, *Simplifying the Measurement of Inventory* (ASU 2015-11), which proposed that inventory should be measured at the lower of cost and net realizable value for inventory that is measured using first-in, first-out (FIFO) or average cost. The main provision of ASU 2015-11 is that an entity should measure inventory at the lower or cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This amendment does not apply to entities that measure inventory using last-in, first-out (LIFO) or the retail inventory method. The standard is effective for public entities for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early application is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the pending adoption of ASU 2015-11 on the consolidated financial statements and has not yet determined the timing at which the Company will adopt the standard.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

4. Property and equipment

Property and equipment consists of the following:

	September 30, 2015	December 31, 2014
Machines and equipment	$240,295	$240,295
Office and computer equipment	166,398	166,398
Software	34,528	34,528
Furniture and fixtures	20,380	20,380
Other assets	2,259	2,259
Total	463,860	463,860
Accumulated depreciation	(458,795)	(456,020)
Net property and equipment	$5,065	$7,840

The aggregate depreciation related to property and equipment charged to operations was $926 and $3,827 for the three months ended September 30, 2015 and 2014, respectively, and $2,775 and $13,312 for the nine months ended September 30, 2015 and 2014, respectively.

5. Intangible assets

Intangible assets consist of the following:

September 30, 2015	December 31, 2014

Patents, at cost	$3,502,135	$3,502,135
Less accumulated amortization	(3,118,690)	(2,888,622)
Net intangible assets	$383,445	$613,513

The aggregate amortization charged to operations was $76,689 for the three months ended September 30, 2015 and 2014, and $230,068 and $230,067 for the nine months ended September 30, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

6. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
Accrued former executive payment	$125,000	$100,000
Accrued legal professional fees	77,827	111,600
Accrued audit and tax preparation	67,500	55,500
Accrued clinical study expenses	62,495	64,464
Accrued inventory	30,927	-
Accrued board of directors fees	12,000	12,000
Accrued other	24,739	25,892
	$400,488	$369,456

7. Notes payable, related parties

The notes payable, related parties were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. The notes payable, related parties bear interest at 6% per annum. Quarterly interest through June 30, 2010, was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal was due August 1, 2015. The notes payable, related parties had an aggregate outstanding principal balance of $5,342,412, net of $30,331 debt discount at September 30, 2015 and $5,372,743 at December 31, 2014, respectively.

On June 15, 2015, the Company and HealthTronics, Inc. entered into an amendment (the "Note Amendment") to amend certain provisions of the notes payable, related parties. The Note Amendment provides for the extension of the due date to January 31, 2017. In connection with the Note Amendment, the Company entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. The notes payable, related

parties will bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company's patents or other intellectual property rights.

In addition, the Company, in connection with the Note Amendment, issued to HealthTronics, Inc. on June 15, 2015, an aggregate total of 3,310,000 warrants (the "Class K Warrants") to purchase shares of the Company's common stock, $0.001 par value (the "Common Stock"), at an exercise price of $0.55 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after ten years.

Accrued interest currently payable totaled $100,123 and $81,864 at September 30, 2015 and December 31, 2014, respectively. Interest expense on notes payable, related parties totaled $100,123 and $81,864 for the three months ended September 30, 2015 and 2014, respectively, and $261,162 and $243,940 for the nine months ended September 30, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

8. Income taxes

The Company files income tax returns in the United States federal jurisdiction and various state and foreign jurisdictions. The Company is no longer subject to United States federal and state and non-United States income tax examinations by tax authorities for years before 2006.

At September 30, 2015, the Company had federal net operating loss ("NOL") carryforwards of $66,038,028 for tax years through the year ended December 31, 2014, that will begin to expire in 2025. The use of deferred tax assets, including federal net operating losses, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, *Income Taxes*, the Company's management believes that there is not sufficient evidence at September 30, 2015 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2015. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including NOL carryforwards.

The Company's ability to use its NOL carryforwards could be limited and subject to annual limitations. In connection with future offerings, the Company may realize a "more than 50% change in ownership" which could further limit its ability to use its NOL carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which NOL carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take advantage of all or portions of its NOL carryforwards for federal income tax purposes.

9. Equity transactions

2014 Private Placement

On March 17, 2014, in conjunction with a private placement of securities (the "2014 Private Placement") with institutional and select accredited investors, the Company issued an aggregate total of 6,210,000 shares of common stock and 6,175 shares of preferred stock (the "Series A Convertible Preferred Stock") for an aggregate total purchase price of $9,280,000. Each share of Series A Convertible Preferred Stock was convertible into 2,000 shares of common stock at the option of the holder. The proceeds received by the Company were $8,562,500, net of offering costs of $717,500.

The Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 23,200,000 warrants (the "Series A Warrants") to purchase shares of common stock at an exercise price of $0.50 per share. Each Series A Warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expire after five years.

In addition, the Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 13,920,000 warrants (the "Series B Warrants") to purchase shares of common stock at an exercise price of $1.50 per share. Each Series B Warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expired in March 2015.

Pursuant to the terms of a registration rights agreement that the Company entered with the investors in connection with the 2014 Private Placement, the Company filed a registration statement with the SEC in April 2014 that covered the shares of common stock and the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock and exercise of the Series A Warrants and Series B Warrants issued to the investors in the 2014 Private Placement. The registration statement was declared effective by the SEC on May 6, 2014.

Kevin A. Richardson, II, chairman of the board of directors of the Company and Acting Chief Executive Officer; Joseph Chiarelli, the former Chief Executive Officer of the Company; and, Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, were purchasers in the 2014 Private Placement of $50,000, $40,000 and $50,000, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

9. Equity transactions (continued)

At the closing of the 2014 Private Placement, the Company paid Newport Coast Securities, Inc., the placement agent for the private placement, and Oppenheimer & Co. Inc., the former placement agent, cash compensation based on the gross proceeds of the private placement and 696,000 Series A Warrants and 417,600 Series B Warrants.

18% Convertible Promissory Notes

During the period January 24, 2014 through March 7, 2014, the Company entered into subscriptions payable for 18% convertible promissory notes, as amended, (the "18% Convertible Promissory Notes") from select accredited investors. Up to $1,000,000 aggregate principal amount of 18% Convertible Promissory Notes were offered by the Company. The Company completed the offering and issued an aggregate $815,000 in convertible notes in March 2014. Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, purchased $110,000 of the convertible notes.

The 18% Convertible Promissory Notes had a nine month term from the subscription date and the note holders could convert into Company common stock at anytime during the term at $0.55 per share. Upon the consummation of a qualified financing, as defined in the convertible note agreements, of $1,000,000 or more by the Company, the principal and interest on the 18% Convertible Promissory Notes would convert into Company common stock equal to the lower of (i) the price of the Company common stock issued in the qualified financing, and (ii) $0.55 per share. The note holders would also receive, if any were issued, warrants or any other security issued in a qualified financing on similar terms to the qualified financing. The 18% Convertible Promissory Notes were unsecured.

The 2014 Private Placement was a qualified financing as defined in the 18% Convertible Promissory Notes. As such, on March 17, 2014, in conjunction with the 2014 Private Placement discussed above, the 18% Convertible Promissory Notes, with an aggregate outstanding principal and accrued interest balance of $822,168, were automatically converted and the holders received in the aggregate 1,644,337 shares of common stock, 2,055,421 Series A Warrants, and 1,233,252 Series B Warrants.

Subscription Agreement

On November 27, 2012, the Company and David N. Nemelka (the "Subscriber"), the brother of a member of the Company's board of directors, entered into a subscription agreement (the "Subscription Agreement") whereby the Subscriber agreed to purchase from the Company, and the Company agreed to sell and issue, a total of 4,000,000 shares of the Company's unregistered common stock at a purchase price equal to $0.25 per share, for an aggregate sales price of $1,000,000 (the "Purchase Price"). The shares are subject to piggy-back registration rights if the Company files a registration statement for an offering of securities.

The Purchase Price was payable to the Company as follows: (i) $50,000 on or before January 31, 2013; (ii) $50,000 on or before February 15, 2013; and (iii) the balance of $900,000 on or before May 27, 2014 (the "Outside Due Date"). The Subscriber could make payments of the Purchase Price at his discretion in minimum installments of $100,000 each, until the Outside Due Date.

In the event that at any time after February 15, 2013, the Company's total available cash should be less than $100,000, the Subscriber would, upon demand of the Company, pay to the Company $100,000 of the then outstanding balance of the Purchase Price, which payment would be due within 30 days of the demand. There was no limit on the number of demands that the Company could make pursuant to this provision of the Subscription Agreement, provided, however, that in no event could the Company provide more than one notice of demand for payment in any 30 day period.

On May 27, 2014, the Subscriber paid the Company the remaining $900,000 and was issued 3,600,000 shares of unregistered common stock of the Company as full settlement of the Subscription Agreement.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

9. Equity transactions (continued)

$278,500 Convertible Promissory Note and Warrants

On February 10, 2014, the Company entered into a financing transaction with an accredited investor for the sale of an 8% convertible promissory note (the "$278,500 Convertible Note") and warrants (the "Class J Warrants") in the principal amount of $278,500, with gross proceeds of $250,000 to the Company after payment of a 10% original issue discount and related professional expenses.

The $278,500 Convertible Note and Class J Warrants were issued pursuant to the terms of a purchase agreement among the Company and the holder. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on August 11, 2014. The convertible note accrued interest at the rate of 8% per annum and included a 10%, or $25,000, original issuance discount. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 60 days was 120% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days. The $278,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of the lower of 75% of the lowest reported sale price of the Company's common stock for the 20 trading days immediately prior to (i) the closing date of the financing, or (ii) 75% of the lowest reported sale price for the 20 days prior the conversion date of the convertible note. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

The Class J Warrants entitle the holder to purchase, in the aggregate, 629,378 shares of the Company's common stock. The Warrants were exercisable upon the six month anniversary of the closing date (August 10, 2014) and expire five years from the closing date. The Class J Warrants have an exercise price equal to $0.4425. The Class J Warrants may be exercised for cash or on a cashless basis. The exercise price of the warrants is subject to adjustment for stock splits, combinations or similar events, and, in this event, the number of shares issuable upon the exercise of the warrant will also be adjusted so that the aggregate exercise price shall be the same immediately before and immediately after the adjustment. In addition, the exercise price is also subject to a "down-round" anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price of the warrants.

In March 2014, the Company repaid the $278,500 Convertible Note in full, which totaled $337,171 with accrued interest and a prepayment penalty of $56,195.

$128,500 Convertible Promissory Note

On December 23, 2013, the Company entered into a financing transaction with an accredited investor for the sale of an 8% convertible promissory note (the "$128,500 Convertible Note") in the principal amount of $128,500, with gross proceeds of $125,000 to the Company after payment of related professional expenses.

The $128,500 Convertible Note was issued pursuant to the terms of a purchase agreement among the Company and the accredited investor. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on September 26, 2014. The convertible note accrued interest at the rate of 8% per annum. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 30 days was 115% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days.

The $128,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 61% of the lowest three reported sale prices of the Company's common stock for the 10 trading days immediately prior to the conversion date. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

9. Equity transactions (continued)

In March 2014, the Company repaid the $128,500 Convertible Note in full, which totaled $158,055, with accrued interest and prepayment penalty of $29,555.

$78,500 Convertible Promissory Note

On February 18, 2014, the Company entered into a second tranche of financing with the accredited investor for the $128,500 Convertible Note for the sale of an 8% Convertible Promissory Note (the "$78,500 Convertible Note") under the same terms as the first tranche in the principal amount of $78,500, with gross proceeds of $75,000 to the Company after payment of related professional expenses.

The $78,500 Convertible Note was issued pursuant to the terms of a purchase agreement among the Company and the accredited investor. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on November 20, 2014. The convertible note accrued interest at the rate of 8% per annum. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 30 days was 115% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days.

The $78,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 61% of the lowest three reported sale prices of the Company's common stock for the 10 trading days immediately prior to the conversion date. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

In March 2014, the Company repaid the $78,500 Convertible Note in full, which totaled $90,275 with accrued interest and prepayment penalty of $11,775.

Consulting Agreements

In February 2014, the Company renewed one consulting contract and entered into three additional consulting agreements for which a portion of the fee for the services performed was paid with Company common stock. The Company issued 0 and 1,035,000 shares of common stock under these agreements for the three months and nine months ended September 30, 2014, respectively. The fair value of the common stock issued to the consultants, based upon the closing market price of the Company's common stock at the dates the common stock was issued, was recorded as a non-cash general and administrative expense of $0 and $743,150 for the three and nine months ended September 30, 2014, respectively. The Company did not have any consulting contracts in 2015 where a portion of the fee for services was to be paid with common stock.

10. Preferred Stock

The Company's Articles of Incorporation authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by the board of directors. On March 14, 2014, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series A Convertible Preferred Stock of the Company (the "Certificate of Designation") with the Nevada Secretary of State. The Certificate of Designation amends the Company's Articles of Incorporation to designate 6,175 shares of preferred stock, par value $0.001 per share, as Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock has a stated value of $1,000 per share. On March 17, 2014, in connection with the 2014 Private Placement, the Company issued 6,175 shares of Series A Convertible Preferred Stock (for a more detailed discussion regarding the 2014 Private Placement, see Note 9).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

10. Preferred Stock (continued)

Under the Certificate of Designation, holders of Series A Convertible Preferred Stock are entitled to receive dividends equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. Such holders will participate on an equal basis per-share with holders of common stock in any distribution upon winding up, dissolution, or liquidation of the Company. Holders of Series A Convertible Preferred Stock are entitled to convert each share of Series A Convertible Preferred Stock into 2,000 shares of common stock, provided that after giving effect to such conversion, such holder, together with its affiliates, shall not beneficially own in excess of 9.99% of the number of shares of common stock outstanding (the "Beneficial Ownership Limitation"). Holders of the Series A Convertible Preferred Stock are entitled to vote on all matters affecting the holders of the common stock on an "as converted" basis, provided that such holder shall only vote such shares of Series A Convertible Preferred Stock eligible for conversion without exceeding the Beneficial Ownership Limitation.

In November and December 2014, the holders of Series A Convertible Preferred Stock converted 5,010 shares of Series A Convertible Preferred Stock into 10,020,000 shares of common stock. On January 6, 2015, the holders of Series A Convertible Preferred Stock converted the remaining 1,165 shares of Series A Convertible Preferred Stock into 2,330,000 shares of common stock. As of September 30, 2015, there were no outstanding shares of Series A Convertible Preferred Stock.

11. Warrants

A summary of the warrant activity as of September 30, 2015 and December 31, 2014, and the changes during the nine months ended September 30, 2015, is presented as follows:

Warrant class	Outstanding as of December 31, 2014	Issued	Exercised	Expired	Outstanding as of September 30, 2015
Class E Warrants	3,576,737	-	-	-	3,576,737

Class F Warrants	300,000	-	-	-	300,000
Class G Warrants	1,503,409	-	-	-	1,503,409
Class H Warrants	1,988,095	-	-	-	1,988,095
Class I Warrants	1,043,646	-	-	-	1,043,646
Class J Warrants	629,378	-	-	-	629,378
Class K Warrants	-	3,310,000	-	-	3,310,000
Series A Warrants	25,951,421	-	-	-	25,951,421
Series B Warrants	15,570,852	-	-	(15,570,852)	-
	50,563,538	3,310,000	-	(15,570,852)	38,302,686

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

11. Warrants (continued)

A summary of the warrant exercise price per share and expiration date is presented as follows:

	Exercise price/share	Expiration date
Class E Warrants	$ 4.00	April 2016
Class F Warrants	$ 0.35	February 2018
Class G Warrants	$ 0.80	July 2018
Class H Warrants	$ 0.80	July 2018
Class I Warrants	$ 0.85	September 2018
Class J Warrants	$ 0.44	February 2019
Class K Warrants	$ 0.55	June 2025
Series A Warrants	$ 0.50	March 2019
Series B Warrants	$ 1.50	March 2015

The exercise price and the number of shares covered by the warrants will be adjusted if the Company has a stock split, if there is a recapitalization of the Company’s common stock, or if the Company consolidates with or merges into another company.

The exercise price of the Class J Warrants, Class K Warrants and the Series A Warrants are subject to a “down-round” anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price of the warrants. The Class J Warrants and Class K Warrants may be exercised on a physical settlement or on a cashless basis. The Series A Warrants may be exercised on a physical settlement basis if a registration statement underlying the warrants is effective. If a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale by the holder of the Series A Warrants, then the holder may exercise the warrants on a cashless basis.

The Class J Warrants, the Class K Warrants, the Series A Warrants and the Series B Warrants are derivative financial instruments. The estimated fair value of the Class J Warrants at the date of grant was $12,776. The related debt discount was accreted to interest expense through the maturity date of the related note. The estimated fair value of the

Class K Warrants at the date of grant was $36,989 and recorded as debt discount, which will be accreted to interest expense through the maturity date of the related notes payable, related parties. The estimated fair values of the Series A Warrants and the Series B Warrants at the date of grant were $557,733 for the warrants issued in conjunction with the 2014 Private Placement and $47,974 for the warrants issued in conjunction with the 18% Convertible Promissory Notes. The fair value of the Series A Warrants and Series B Warrants were recorded as equity issuance costs in 2014, a reduction of additional paid-in capital. The Series B Warrants expired unexercised in March 2015.

The estimated fair values were determined using a binomial option pricing model based on various assumptions. The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of derivative liabilities. Various factors are considered in the pricing models the Company uses to value the warrants, including the Company's current common stock price, the remaining life of the warrants, the volatility of the Company's common stock price, and the risk-free interest rate. In addition, as of the valuation dates, management assessed the probabilities of future financing and other re-pricing events in the binominal valuation models.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

11. Warrants (continued)

A summary of the changes in the warrant liability as of September 30, 2015 and December 31, 2014, and the changes during the three and nine months ended September 30, 2015, is presented as follows:

	Class J Warrants	Class K	Series A	Series B