SANUWAVE Health, Inc.
Form 10-K
March 30, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to

Commission File Number 000-52985

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**20-1176000**
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
11475 Great Oaks Way, Suite 150	**30022**

Alpharetta, GA
(Address of principal executive offices) (Zip Code)

(770) 419-7525

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
N/A	**N/A**

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

1

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the registrant’s common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation only, that the registrant’s directors, executive officers and greater than 10% shareholders are affiliates of the registrant), based upon the closing sale price of the registrant’s common stock on June 30, 2015, the last business day of the registrant’s most recently completed second fiscal quarter, was $9.5 million.

As of March 23, 2016, there were issued and outstanding 96,000,308 shares of the registrant’s common stock.

SANUWAVE Health, Inc.

Table of Contents

PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K of SANUWAVE Health, Inc. and its subsidiaries ("SANUWAVE" or the "Company") contains forward-looking statements. All statements in this Annual Report on Form 10-K, 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, clinical trial results, regulatory approvals, 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 "continue," the negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in this report, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Other risks and uncertainties are and will be disclosed in the Company's prior and future Securities and Exchange Commission (the "SEC") filings. These and many other factors could affect the Company's future financial condition and operating results and could cause actual results to differ materially from expectations based on forward-looking statements made in this document or elsewhere by the Company or on its behalf. The Company undertakes no obligation to revise or update any forward-looking statements.

Except as otherwise indicated by the context, references in this Annual Report on Form 10-K to "we," "us" and "our" are to the consolidated business of the Company.

Item 1. BUSINESS

Overview

We are an acoustic pressure shock wave technology company using a patented system of noninvasive, high-energy, acoustic pressure shock waves for indications such as regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of skin, musculoskeletal tissue and vascular structures. Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. The results of these clinical studies will be submitted to the FDA, after our in-person meeting to discuss the submission strategy in late April or early May, for possible approval in 2016.

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/endovascular 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 musculoskeletal 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, Asia and Asia/Pacific. 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

cardiovascular applications for removing plaque due to atherosclerosis in arterial blood vessels (peripheral and heart) and improving heart muscle performance through improved blood circulation.

In addition to healthcare uses, our high-energy, acoustic pressure shock waves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters, for sterilizing 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 shock waves to produce compressive and tensile stresses on cells and tissue structures. These mechanical stresses at the tissue and cellular levels have been shown in pre-clinical work to promote angiogenic responses as well as modulation of the body's inflammatory response, which in turn initiates the healing cascade. Furthermore, the pre-clinical work also showed that our high-energy acoustic pressure shock waves 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 also 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 shock waves 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 plantar fasciitis of the foot in 2000 and for elbow tendonitis in 2003. Previously, acoustic pressure shock waves 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 the care status of “golden standard” for the treatment of kidney stones.

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 musculoskeletal 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, Asia and Asia/Pacific.

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 skin, musculoskeletal tissue 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 Americas, Europe, Middle East, Australia and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and noninvasive (extracorporeal) treatment options in wound healing, orthopedic injuries, plastic/cosmetic uses and cardiovascular 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) granted approval of our Investigational Device Exemption (IDE) to conduct two double-blinded, randomized clinical trials utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers.

The dermaPACE device completed its initial Phase III, IDE clinical 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 below.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical trial. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted initial clinical trial. 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 supplemental clinical trial, substantially fewer patients were required than would otherwise be the case while still ensuring adequate statistical power. This approach saved significant time and preserved scientific rigor.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan for the supplemental clinical trial incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the initial clinical trial (discussed above). Similar to the initial trial, four dermaPACE procedures are administered

during the first two weeks following subject enrollment. In the supplemental clinical trial, however, up to four 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.

The patient enrollment began in June 2013 for the supplemental clinical trial and by April 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 DMC had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the supplemental 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.

In May 2015, the DMC performed an analysis on the 130 patients 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 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 had 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. We decided to stop any further enrollment in the supplemental clinical trial after this review.

We 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.

In June 2015 we met with the FDA to discuss analysis strategy for the data for the supplemental clinical trial and for the combined data of the two studies. In addition to the original data analysis plan for wound closure at 12 weeks, we proposed to analyze wound closure data at time points beyond 12 weeks, up to and including 24 weeks as we had positive results in the first study of 206 patients completed in 2011 at the 20 week endpoint. The FDA agreed to the additional analyses and stressed that their review and eventual decision will be based upon the totality of the data, both for efficacy and safety.

In October 2015 after freezing and locking the data, we began to perform data analysis. At the 12 week endpoint a total of 39 out of 172 (22.7%) of dermaPACE patients had complete wound closure, compared to 30 out of 164 (18.3%) in the control group. As expected, there was no statistically significant difference in wound closure at the 12 week follow up between the dermaPACE and control group; however, in subsequent visits a trend towards significance was shown resulting in a significant difference by the 20 week endpoint that was maintained through the end of the study. At the 24 week endpoint, the rate of wound closure in the dermaPACE patients was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023. Additionally, there were no serious or related adverse events associated with the 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 submission plans to the FDA. Working with MCRA, we have submitted to the FDA a Pre-Submission package, presenting possible submission pathways and have requested an in-person meeting to discuss the submission strategy. We expect this meeting to occur in late April or early May 2016. A formal submission will be presented to the FDA after this meeting.

Finally, 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. The dermaPACE is also licensed for sale in Canada, Australia and New Zealand.

We are actively marketing the dermaPACE to the European Community, Canada and Asia/Pacific, utilizing distributors in select countries.

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 in the United States for our lead product candidate, dermaPACE, for the treatment of 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 and in addition, chronic diabetic foot ulcers and pressure ulcers are often slow-to-heal wounds, which often fail to heal for many months, and sometimes, for several years. 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. These wounds often develop due to a patient's impaired vascular and tissue repair capabilities. 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 chronic 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 treatments are designed to elicit the body's own healing response and, 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 approval 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. In 2013, we obtained approval from South Korea's Ministry of Food and Drug Safety to market orthoPACE in that country.

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 musculoskeletal 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 kinds of 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 acoustic pressure shock wave 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 that high-energy, acoustic pressure shock waves can be used to clean, in an energy efficient manner, contaminated fluids from impurities, bacteria, viruses and other harmful micro-organisms, which provides opportunities for our technology in cleaning industrial and domestic/municipal waters. Based on the same principles of action of the acoustic pressure shock waves 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 that the acoustic pressure shock waves 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 trapped oil in the underground reservoir. Through the use of our high-energy, acoustic pressure shock waves the efficiency can be improved and in the same time the environmental impact of the fracking process can be reduced. Furthermore, we believe our technology can be used for enhanced oil recovery (EOR) based on the changes in oil flow characteristics resulting from acoustic pressure shock wave stimulation, as a tertiary method of oil recovery from older oil fields.

Additionally, we demonstrated through two studies performed at Montana State University that high-energy, acoustic pressure shock waves 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 obesity, diabetes, vascular and heart disease, as well as sports injuries, we believe that Medicare and private insurers have become aware of the high costs and expenditures associated with the adjunctive therapies being utilized for wound healing and orthopedic conditions that have 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 acoustic pressure shock wave technology for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of skin, musculoskeletal tissue and vascular structures. Our lead regenerative product in the United States is the dermaPACE device for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. The results of these clinical studies will be submitted to the FDA, after our in-person meeting to discuss the submission strategy in late April or early May, for possible approval in 2016.

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 cardiovascular 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 in the United States for our lead product candidate, dermaPACE, for the treatment of diabetic foot ulcers, which we believe represents a large, unmet need. The FDA granted approval of our Investigational Device Exemption (IDE) to conduct two double-blinded, randomized clinical trials utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. Management has completed the analysis phase of clinical trial data from both trials 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 skin, musculoskeletal tissue and vascular structures.

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

License and seek partnership opportunities for our non-medical acoustic pressure shock wave technology platform, know-how and extensive patent portfolio.

We intend to use our acoustic pressure shock wave technology and know-how for non-medical uses, including energy, food, water cleaning and other 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 scientific 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 2015 and 2014 and recorded stock-based compensation expense of $11,107 and $35,625 for the years ended December 31, 2015 and 2014, 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 commercialize the 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 for both the generator boxes and applicators and perform the final product testing and certifications internally.

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 significant portion 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 acoustic pressure shock wave 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 devices. Our United States patents also include patent claims directed to methods of using acoustic pressure shock waves, including devices such as our products, to treat ischemic conditions, spinal cord scar tissue and spinal injuries, bone fractures and osteoporosis, 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 acoustic pressure shock wave treatment devices, and various methods of using acoustic pressure shock waves. Such patent-pending methods include, for example, using acoustic pressure shock 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 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 for most of our patent portfolio issued before 2009 to utilize acoustic pressure shock wave 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, Canada and under the Madrid Protocol), angioPACE® (Australia, European Community and Switzerland), PACE® (Pulsed Acoustic Cellular Expression) (United States, European Community, China, Hong Kong, Singapore, Switzerland, Taiwan, and Canada), orthoPACE® (United States and European Community), DAP® (Diffused Acoustic Pressure) (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), and Reflectrode® (Germany and Switzerland).

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 assisted HealthTronics as an informer of misappropriation by a Swiss company called 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. As a result of this action, SwiTech was forced into bankruptcy. We are currently pursuing the misappropriation by another Swiss company called SwiTalis 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 medical technologies developed by Kinetic Concepts, Inc. (“KCI”), Organogenesis, Inc., Smith & Nephew plc, Derma Sciences, Inc., MiMedx Group, Inc., Osiris Therapeutics, Inc., Molnlycke Health Care, and Systagenix Wound Management (US), Inc. (now owned by KCI) 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, Electro Medical Systems (EMS) S.A., CellSonic Medical 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. 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.

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.

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.

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 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 current good manufacturing practice (cGMP), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with cGMP 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 for both hospital and in-office procedures. 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, 2015 and 2014, we spent $2,172,819 and $3,000,807, respectively, on research and development activities which consists of clinical trial expenses for the dermaPACE diabetic foot ulcer clinical study in the United States and research costs by partnering universities for non-medical uses of the PACE technology.

Employees

As of March 25, 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.

Item 1A. RISK FACTORS

Risks Related to our Business

Our recurring losses from operations and dependency upon future issuances of equity or other financing to fund ongoing operations have raised substantial doubts as to our ability to continue as a going concern. We will be required to raise additional funds to finance our operations and remain a going concern; 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. We expect to devote substantial resources to complete our FDA submission of the Phase III clinical trial data for the dermaPACE device to treat diabetic foot ulcers. Because of the significant time it could take for us to obtain approval from regulatory authorities, assuming positive feedback from the FDA on our pre-submission strategy, and successfully commercialize our product, we will require additional capital resources. We incurred a net loss of $4,810,285 and $5,974,080 for the years ended December 31, 2015 and 2014, respectively. These operating losses create uncertainty about our ability to continue as a going concern.

Subsequent to year-end, on March 11, 2016, we completed an equity offering of securities for a gross total purchase price of $1,529,750. At December 31, 2015, we had cash and cash equivalents totaling $152,930 and negative working capital of $851,805. For the years ended December 31, 2015 and 2014, our net cash used by operating activities was $3,473,456 and $6,678,369, respectively. Management expects the cash used in operations for the Company during the first two quarters of 2016 will be approximately $175,000 to $225,000 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, in late April.

The continuation of our business is dependent upon raising additional capital during or before the third quarter of 2016 to fund operations. Management’s plans are to obtain additional capital in 2016 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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 as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

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

For the year ended December 31, 2015, we had a net loss of $4,810,285 and used $3,473,456 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. As of December 31, 2015, we had an accumulated deficit of $92,994,408 and a total stockholders' deficit of $5,877,836. 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 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:

- 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;
the impact of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the PPACA) on our operations,
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. Any acquisition 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. As of December 31, 2015, both Prides Capital and NightWatch Capital have liquidated, 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 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;
- the reimbursement for our products is difficult to obtain or is too low, which can hinder the introduction and acceptance of our products in the market;
- 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 or environmental 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 eight 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 and 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 and our products and product candidates, 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 and other international regulatory bodies to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA and other international regulatory bodies will not indentify compliance issues that may disrupt production or distribution, or require substantial resources to correct.

The FDA's requirements and international regulatory body requirements may change and additional 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 clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.

We engage a clinical research organization (CRO) and other third party vendors to assist in the conduct of our clinical trials. 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 clinical trials, the commercial prospects for the product could be harmed and our ability to generate product revenues would be delayed or prevented. Any failure of the CRO and other third party vendors to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services they provide 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 the 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 trials, 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 trials 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 pricing 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, including the recently enacted legislation to reform the United States healthcare system, 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, began in 2013 but a two year moratorium has been issued for sales during 2016 and 2017;
- 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 the United States and other markets. We could experience an adverse impact on our operating results due to increased pricing pressure these 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 may conduct experiments 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, 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 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 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 that 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 us 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 may be owned by us 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 us or licensed to us or that may in the future be owned by us or impede 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 us or against us may result in determinations that patents that have been issued to us 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 clinical 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 on-going 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 (the 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 common stock may be impaired by the potential issuance of 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.

On January 12, 2016, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series B Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 293 shares of our preferred stock as Series B Convertible Preferred Stock. The holders of Series B Convertible Preferred Stock will participate on an equal basis per-share with holders of our common stock in any distribution upon winding up, dissolution, or liquidation. Holders of Series B Convertible Preferred Stock are entitled to convert each share of Series B Preferred Stock into 2,000 shares of common stock. Holders of the Series B Preferred Stock are entitled to vote on all matters affecting the holders of the common stock of the Company on an “as converted” basis, provided that the holder of such Series B Preferred Stock does not hold in excess of 9.99% of our common stock at the time of measurement.

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, and in 2014, 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. 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 $9,022, 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 of $11,278 (125% of the most recent current rent) for the first two months and monthly rent of $13,534 (150% of the most recent current rent) for each month thereafter.

Item 3. 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.

Item 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERSAND ISSUER PURCHASES OF EQUITY SECURITIES

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**
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

Holders of Common Stock

As of March 23, 2016, there were 118 holders of record of the Company's common stock.

Dividends

The Company has never declared or paid any cash dividends on its common stock. The Company intends to retain future earnings, if any, to finance the expansion of its business. As a result, the Company does 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	10,073,385	$ 0.62	3,758,281
Total	10,073,385	$ 0.62	3,758,281

Stock Incentive Plans

During 2006, the Company 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.

Item 6. SELECTED FINANCIAL DATA

Not required under Regulation S-K for “smaller reporting companies”.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are an acoustic pressure shock wave technology company using a patented system of noninvasive, high-energy, acoustic pressure shock waves for indications such as regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of skin, musculoskeletal tissue and vascular structures. Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. The results of these clinical studies will be submitted to the FDA, after our in-person meeting to discuss the submission strategy in late April or early May, for possible approval in 2016.

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/endovascular 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 musculoskeletal 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, Asia and Asia/Pacific. 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
cardiovascular applications for removing plaque due to atherosclerosis in arterial blood vessels (peripheral and heart) and improving heart muscle performance through improved blood circulation.

In addition to healthcare uses, our high-energy, acoustic pressure shock waves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters, for sterilizing 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) granted approval of our Investigational Device Exemption (IDE) to conduct two double-blinded, randomized clinical trials utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers.

The dermaPACE device completed its initial Phase III, IDE clinical 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 below.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical trial. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted initial clinical trial. 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 supplemental clinical trial, substantially fewer patients were required than would otherwise be the case while still ensuring adequate statistical power. This approach saved significant time and preserved scientific rigor.

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

The patient enrollment began in June 2013 for the supplemental clinical trial and by April 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 DMC had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the supplemental 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.

In May 2015, the DMC performed an analysis on the 130 patients 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 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 had 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. We decided to stop any further enrollment in the supplemental clinical trial after this review.

We 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.

In June 2015 we met with the FDA to discuss analysis strategy for the data for the supplemental clinical trial and for the combined data of the two studies. In addition to the original data analysis plan for wound closure at 12 weeks, we proposed to analyze wound closure data at time points beyond 12 weeks, up to and including 24 weeks as we had positive results in the first study of 206 patients completed in 2011 at the 20 week endpoint. The FDA agreed to the additional analyses and stressed that their review and eventual decision will be based upon the totality of the data, both for efficacy and safety.

In October 2015 after freezing and locking the data, we began to perform data analysis. At the 12 week endpoint a total of 39 out of 172 (22.7%) of dermaPACE patients had complete wound closure, compared to 30 out of 164 (18.3%) in the control group. As expected, there was no statistically significant difference in wound closure at the 12 week follow up between the dermaPACE and control group; however, in subsequent visits a trend towards significance was shown resulting in a significant difference by the 20 week endpoint that was maintained through the end of the study. At the 24 week endpoint, the rate of wound closure in the dermaPACE patients was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023. Additionally, there were no serious or related adverse events associated with the 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 submission plans to the FDA. Working with MCRA, we have submitted to the FDA a Pre-Submission package, presenting possible submission pathways and have requested an in-person meeting to discuss the submission strategy. We expect this meeting to occur in late April. A formal submission will be presented to the FDA after this meeting.

Financial Overview

We expect to devote substantial resources to complete our FDA submission of the Phase III clinical trial data for the dermaPACE device to treat diabetic foot ulcers. Because of the significant time it could take for us to obtain approval from regulatory authorities, assuming positive feedback from the FDA on our pre-submission strategy, and successfully commercialize our product, we will require additional capital resources. We incurred a net loss of $4,810,285 and $5,974,080 for the years ended December 31, 2015 and 2014, respectively. These operating losses create uncertainty about our ability to continue as a going concern.

Subsequent to year-end, on March 11, 2016, we completed an equity offering of securities for a gross total purchase price of $1,529,750. At December 31, 2015, we had cash and cash equivalents totaling $152,930 and negative working capital of $851,805. For the years ended December 31, 2015 and 2014, our net cash used by operating activities was $3,473,456 and $6,678,369, respectively. Management expects the cash used in operations for the Company during the first two quarters of 2016 will be approximately $175,000 to $225,000 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, in late April.

The continuation of our business is dependent upon raising additional capital during or before the third quarter of 2016 to fund operations. Management's plans are to obtain additional capital in 2016 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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 as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

Since our inception, we have incurred losses from operations each year. As of December 31, 2015, we had an accumulated deficit of $92,994,408. 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 incurred a net loss of $4,810,285 and $5,974,080 during the years ended December 31, 2015 and 2014, respectively. These operating losses create an uncertainty about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing, as discussed above, will provide the necessary funding for us to continue as a going concern for the next year.

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 2 to our consolidated financial statements filed with this Annual Report on Form 10-K, 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 revenues 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, research collaborators 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 and collaborators, 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.

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 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*, 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*, 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* , 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 Years ended December 31, 2015 and 2014

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2015 were $965,501, compared to $847,367 for the same period in 2014, an increase of $118,134, or 14%. 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 2015 is primarily due to an increase in sales of orthoPACE devices in Asia/Pacific and the European Community, as compared to the prior year, as well as higher sales of new and refurbished applicators.

Cost of revenues for the year ended December 31, 2015 were $284,962, compared to $219,975 for the same period in 2014. Gross profit as a percentage of revenues was 70% for the year ended December 31, 2015, compared to 74% for the same period in 2014. The decrease in gross profit as a percentage of revenues in 2015 was due to a higher percentage of revenues being from the sale of devices in 2015, as compared to 2014, which have a lower margin than new and refurbished applicators.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2015 were $2,172,819, compared to $3,000,807 for the same period in 2014, a decrease of $827,988, or 28%. Research and development expenses include the costs associated with the dermaPACE clinical trial, which incurred the more costly enrollment phase in 2014 that totaled $939,649 and $1,772,444 for the years ended December 31, 2015 and 2014, respectively.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2015 were $2,735,129, as compared to $3,269,033 for the same period in 2014, a decrease of $533,904, or 16%. The decrease in general and administrative expenses in 2015, as compared to 2014, was primarily due a decrease of $743,150 in the cost for stock issued for consulting services as a result of less financial and investors relations consultants utilized in 2015 as compared to the prior year. This is partially offset by $354,000 of stock based compensation expense due to stock options issued to employees, board of directors and medical advisors in October 2015.

Depreciation and Amortization

Depreciation for the year ended December 31, 2015 was $3,612, compared to $14,286 for the same period in 2014, a decrease of $10,674, or 75%. The decrease was due to no purchase of new assets in 2015.

Amortization for the years ended December 31, 2015 and 2014 was $306,757 and $306,756, respectively.

Other Income (Expense)

Other income (expense) was a net expense of $372,507 for the year ended December 31, 2015 as compared to a net expense of $10,590 for the same period in 2014, an increase of $361,917 in the net expense. The net expense in 2014 included a non-cash gain of $458,857 for a valuation adjustment on outstanding warrants, as compared to a non-cash gain of $58,515 in 2015. This is partially offset by lower total interest expense due to no outstanding promissory notes in 2015.

Provision for Income Taxes

At December 31, 2015, we had federal net operating loss carryforwards of $70,096,802 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, 2015 was $4,810,285, or ($0.08) per basic and diluted share, compared to a net loss of $5,974,080, or ($0.12) per basic and diluted share, for the same period in 2014, a decrease in the net loss of $1,163,795, or 19%. The decrease in the net loss was primarily a result of decrease in operating expenses and gain on warrant valuation adjustment.

We anticipate that our operating losses will continue over the next few years as we prepare our FDA submission for the dermaPACE device for the treatment of diabetic foot ulcers but if we obtain FDA approval and are able to successfully commercialize, market and distribute the dermaPACE device, then we hope to partially or completely offset these losses within the next few years.

Liquidity and Capital Resources

We expect to devote substantial resources to complete our FDA submission of the Phase III clinical trial data for the dermaPACE device to treat diabetic foot ulcers. Because of the significant time it could take for us to obtain approval from regulatory authorities, assuming positive feedback from the FDA on our pre-submission strategy, and successfully commercialize our product, we will require additional capital resources. We incurred a net loss of $4,810,285 and $5,974,080 for the years ended December 31, 2015 and 2014, respectively. These operating losses create uncertainty about our ability to continue as a going concern.

Subsequent to year-end, on March 11, 2016, we completed an equity offering of securities for a gross total purchase price of $1,529,750. At December 31, 2015, we had cash and cash equivalents totaling $152,930 and negative working capital of $851,805. For the years ended December 31, 2015 and 2014, our net cash used by operating activities was $3,473,456 and $6,678,369, respectively. Management expects the cash used in operations for the Company during the first two quarters of 2016 will be approximately $175,000 to $225,000 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, in late April, or early May.

The continuation of our business is dependent upon raising additional capital during or before the third quarter of 2016 to fund operations. Management's plans are to obtain additional capital in 2016 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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 as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be 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.

For the years ended December 31, 2015 and 2014, net cash used by operating activities was $3,473,456 and $6,678,369, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for the year ended December 31, 2015, as compared to the same period for 2014, of $3,204,913, or 48%, was primarily due to the decreased total operating expenses in 2015, as compared to 2014, of $1,372,565, the lower gain on warrant valuation in 2015, as compared to 2014, of $400,342 and the increase of accounts payable and accrued expenses in 2015 of $267,344. Net cash provided by investing activities in 2015 was $100,000 from the sale of assets held for sale. Net cash used by investing activities was $8,859 in 2014 from the purchase of property and equipment. Net cash provided by financing activities for the year ended December 31, 2014 was $10,071,149, which 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. There was no net cash provided by financing activities in 2015. Cash and cash equivalents decreased by $3,394,141 for the year ended December 31, 2015 and cash and cash equivalents increased by $3,364,756 for the year ended December 31, 2014.

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, related parties.

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. 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.

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 was due August 1, 2015. Accrued interest on the notes which matured in August 2015 totaled $1,372,743 at December 31, 2015 and 2014.

On June 15, 2015, we entered into an amendment (the "Note Amendment") with HealthTronics, 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 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, in connection with the Note Amendment, we 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.

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 August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU provides guidance on management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures in the notes to the financial statements. The amendments in this ASU should help reduce the diversity in the timing and content of disclosures in the notes to the financial statements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The implementation of this ASU is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In April 2015, the FASB issued ASU 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. This ASU provides guidance that simplifies the presentation of debt issuance costs by amending the accounting guidance to require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability. The amendments are consistent with the accounting guidance related to debt discounts. This guidance is effective for the first interim or annual period beginning after December 15, 2015. The Company will adopt this guidance in the first quarter of fiscal 2016. The Company is currently assessing the impact of this guidance on its consolidated financial statements.

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.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. This ASU provides guidance that simplifies the presentation of deferred income taxes. This ASU requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The implementation of this ASU is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize the most leases on the balance sheet. The provisions of this guidance are effective for the annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. Management is evaluating the requirements of this guidance and has not yet determined the impact of the adoption on the Company's financial position or results of operations.

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

Due to the fact that 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.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required under Regulation S-K for "smaller reporting companies".

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required by this item and an index thereto are contained in Part IV, Item 15 of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We carried out an evaluation under the supervision and with the participation of our management, including our Acting Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2015. Based on this evaluation, the Acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not operating effectively as of December 31, 2015. Our disclosure controls and procedures were not effective because of the "material weakness" described below under "Management's Annual Report on Internal Control over Financial Reporting," which were previously reported in the prior year, are still in the process of being remediated below as described below under "Management's Plan to Remediate Material Weakness."

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Management, with the participation of the Acting Chief Executive Officer (principal executive officer) and the Chief Financial Officer (principal financial and accounting officer), evaluated the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework (2013).

A "material weakness" is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. As a result of its review, management concluded that we had a material weakness in our internal control over financial reporting process for the lack of internal expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions related to complex financial instruments and derivatives.

Management believes the material weakness identified above was due to the complex and non-routine nature of the Company's complex financial instruments and derivatives.

Management's Plan to Remediate Material Weakness

Management has developed a remediation plan to address the material weakness related to its processes and procedures surrounding the accounting for complex financial instruments and derivatives. Implementation of the remediation plan is in process and consists of, among other things, redesigning the procedures to enhance its

identification, capture, review, approval and recording of contractual terms included in contractual debt and equity arrangements. Management is also pursuing obtaining additional interpretive guidance on identifying and accounting for complex financial instruments and derivatives as well as engaging, as necessary, an outside consultant to assist in the application of United States GAAP to complex transactions, including the accounting for derivatives. These measures are intended both to address the identified material weakness and to enhance our overall internal control environment. While management has completed the design of these controls, management has not yet had an instance to test the operating effectiveness of these enhanced internal controls.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in the Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have been changes in our internal control over financial reporting that occurred during the period covered by this report that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting. Management has designed changes to its controls as discussed above in Management's Plan to Remediate Material Weakness, however, management has not yet had an instance to test the operating effectiveness of these changes.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

MANAGEMENT

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 E. Sundstrom	46	Chief Financial Officer
Peter Stegagno	56	Vice President, Operations
Iulian Cioanta, PhD	53	Vice President, Research and Development
John F. Nemelka	50	Director
Alan L. Rubino	61	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 served as managing partner of Prides Capital LLC, an investment management firm, until its liquidation in September 2015.

Lisa E. 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.

Peter Stegagno joined the Company as Vice President, Operations in March 2006. Mr. Stegagno brings to the Company sixteen years experience in the medical device market encompassing manufacturing, design and development, quality assurance and international and domestic regulatory affairs. He most recently served as Vice President of Quality and Regulatory Affairs for Elekta, and other medical device companies including Genzyme Biosurgery. Before focusing on the medical field, Mr. Stegagno enjoyed a successful career encompassing production roles in the space industry, including avionics guidance systems for military applications and control computers for the space shuttle. Mr. Stegagno graduated from Tufts University with a Bachelor of Science degree in Chemical Engineering.

Iulian Cioanta, PhD joined the Company in June 2007 as Vice President of Research and Development. Dr. Cioanta most recently served as Business Unit Manager with Cordis Endovascular, a Johnson & Johnson company. Prior to that, Dr. Cioanta worked as Director of Development Engineering with Kensey Nash Corporation, Research Manager at AgroMed Inc. and Project Manager and Scientist with the Institute for the Design of Research Apparatus. Dr. Cioanta also worked in academia at Polytechnic University of Bucharest in Romania, Leicester University in the United Kingdom and Duke University in the United States. Dr. Cioanta received a Master of Science degree in Mechanical Engineering and Technology form the Polytechnic University of Bucharest and he earned his PhD degree in Biomedical Engineering from Duke University in the field of extracorporeal shock wave lithotripsy.

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 served as its Managing Principal since its incorporation in July 2001 until its liquidation in December 2015. 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.

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

Recent Developments

The Company's current board of directors consists of three members, one of whom has been determined by the board to be "independent" as defined under the rules of the NASDAQ stock market. The Company expects to add additional independent directors in 2016.

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. The Company's board of directors has determined that it is currently in the best interest of the Company and its shareholders to separate the roles of chairman of the board and 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.

The Company believes, however, 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 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 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 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 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.

Item 11. EXECUTIVE COMPENSATION

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
Lisa E. Sundstrom [2] Chief Financial Officer (principal financial officer)	2015	$111,587	-	$53,016[3]	-	-	-	$ 11,895	$176,498
	2014	$99,419	$10,000	$11,917[3]	-	-	-	$ 12,237	$133,573
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
Barry J. Jenkins Chief Financial Officer and COO	2015	$143,160[5]	-	-	-	-	-	$ 10,234	$153,394
	2014	$245,417	-	$23,833[3]	-	-	-	$ 18,178	$287,428

(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) Ms. Sundstrom was named Interim Chief Financial Officer as of July 31, 2015 and named Chief Financial Officer in December 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.

(5) Mr. Jenkins resigned as Chief Financial Officer and COO as of July 31, 2015.

Employment Agreements

Barry J. Jenkins

General Terms. Barry Jenkins is the former Chief Financial Officer of the Company. Mr. Jenkins joined the Company to serve as the Chief Financial Officer commencing on April 10, 2006 with no specific duration. Mr. Jenkins is no longer employed by the Company as of July 31, 2015.

Pursuant to his employment agreement, 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 his compensation was subject to adjustment 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 contained an agreement not to compete, which covered the term of employment and two years thereafter, and a confidentiality provision, which is indefinite.

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.

Termination. Mr. Jenkins' employment was subject to termination by either party at any time and for any reason; provided that Mr. Jenkins was required to give the Company at least 30 days advance written notice of any resignation. If Mr. Jenkins were terminated by the Company for cause or resigned without good reason, he would have been entitled to receive his (1) base salary through the termination date, (2) any annual bonus earned, but unpaid as of the date of termination for the immediately preceding fiscal year, (3) reimbursement for certain unreimbursed business expenses, and (4) such employee benefits to which he might be entitled under the employee benefit plans of the Company. If Mr. Jenkins were terminated by the Company without cause or resigned for good reason, he would have been entitled to receive all of the above plus (1) subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, continued payment of the base salary until six months following the date of termination, and (2) continued coverage of him and his beneficiaries under the Company's health insurance programs for a period of up to six months.

Change of Control. In addition to any other termination benefits that Mr. Jenkins was be entitled to receive, if a change of control occurs, then subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, Mr. Jenkins would have been entitled to receive 100% accelerated vesting of his options.

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. (the "2006 Plan"). 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 three 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 12,500,000 shares of common stock reserved for grant at December 31, 2015 and had 8,500,000 shares of common stock reserved for grant at December 31, 2014.

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 that 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, 2015, there were 3,758,281 shares of common stock available for grant under the Stock Incentive Plan. For the years ended December 31, 2015 and 2014, there were 1,750,000 and 50,000 options, respectively, granted to the Company's executive officers under the Stock Incentive Plan.

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/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market 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	115,000 (1)	-	-	$ 0.35	02/21/2023	-	-	-	-
Chairman of the Board and Co-Chief Executive Officer (principal executive officer)	452,381 (3)	-	-	$ 0.11	10/1/2025	-	-	-	-
	297,619 (3)	-	-	$ 0.50	10/1/2025	-	-	-	-
Lisa Sundstrom	65,000 (1)	-	-	$ 0.35	02/21/2023	-	-	-	-
Chief Finanical Officer (principal executive officer)	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	-	-	-	$95,524
John F. Nemelka	$16,000	-	$26,508	-	-	-	$42,508
Alan L. Rubino	$16,000	-	$26,508	-	-	-	$42,508

(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.

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 – 865,000, John F. Nemelka – 365,000 and Alan L. Rubino – 350,000.

Discussion of Director Compensation

Effective January 1, 2013, the Company began to compensate its three outside directors at an annual rate of $16,000 each. 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 and 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 September 3, 2013, the Company issued 100,000 options to purchase the Company’s common stock at $0.65 per share to non-employee director Alan L. Rubino. On February 21, 2013, the Company, by mutual agreement with all the 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. Kevin A. Richardson, II, and John F. Nemelka, each cancelled 15,000 options and were each issued 115,000 options at an exercise price of $0.35 per share.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information, as of March 25, 2016, with respect to the beneficial ownership of the Company's outstanding common stock by (i) any holder of more than five percent, (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]	9,856,240	10.1%
John F. Nemelka [4]	1,896,773	2.0%
Alan Rubino [5]	350,000	0.3%
Lisa E. Sundstrom [6]	590,000	0.6%
All directors and executive officers as a group (4 persons)	12,693,013	13.0%
5% Beneficial Owner:		
Jerome Gildner [7]	13,333,334	13.0%
RA Capital Healthcare Fund, L.P. [8]	6,885,346	7.1%
Prides Capital Fund I, LP [9]	6,467,733	6.7%

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

(2) Applicable percentage ownership is based on 96,000,308 shares of common stock outstanding as of March 23, 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 March 23, 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) Consists of options to purchase up to 590,000 shares of common stock.

(7) Based on records of the Company.

(8) 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, and (b) 1,007,895 shares of shares of common stock issued upon the conversion of Series A Warrants 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.

(9) 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 (3).

Securities Authorized for Issuance Under Equity Compensation Plans

Information on securities authorized for issuance under the Company's equity compensation plans can be found in Item 5 under the same caption in this Annual Report on Form 10-K.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

Other than as described below, for the fiscal years ended December 31, 2015 and 2014, there were no transactions with related persons required to be disclosed in this report.

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.

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 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 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”). 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 thirty (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 thirty (30) day period. 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. 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.

Director Independence

Our board of directors has determined that Alan L. Rubino qualifies as independent director based on the NASDAQ stock market definition of “independent director.” Our board of directors has determined that our other two outside directors, Kevin A. Richardson, II and John F. Nemelka, do not qualify as independent directors based on the NASDAQ stock market definition of “independent director.” There are no family relationships among any of the directors or executive officers of the Company.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table summarizes the fees that we have paid or accrued for audit and other services provided by our principal independent registered public accounting firm, BDO USA, LLP, for the years ended December 31, 2015 and 2014:

Fee Category	**2015**	**2014**
Audit fees	$138,712	$133,127
Tax fees	18,005	12,814
Audit related fees	-	-
All other fees	-	-
Total fees	$156,717	$145,941

For purposes of the preceding table:

Audit fees consist of fees for the annual audit of our consolidated financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with statutory and regulatory filings and consents related to capital markets transactions and engagements for those fiscal years.

Tax fees consist of fees for tax compliance, tax advice and tax planning services for those fiscal years.

Audit related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit or review.

All other fees consist of fees for all other products and services.

The board of directors must pre-approve all audits and permitted non-audit services to be provided by our principal independent registered public accounting firm unless an exception to such pre-approval exists under the Exchange Act or the rules of the SEC. Each year, the board of directors approves the retention of the independent auditor to audit our consolidated financial statements, including the associated fee. At this time, the board of directors evaluates other known potential engagements of the independent auditor, including the scope of audit-related services, tax services and other services proposed to be performed and the proposed fees, and approves or rejects each service, taking into account whether the services are permissible under applicable law and the possible impact of each non-audit service on the independent auditor’s independence from management.

Audit Committee Report

The audit committee oversees the accounting and financial reporting processes of the Company on behalf of the board of directors. Management has primary responsibility for the Company’s financial statements, financial reporting process and internal controls over financial reporting. The independent auditors are responsible for performing an independent audit of the Company’s consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). The audit committee's responsibility is to select the independent auditors and monitor and oversee the accounting and financial reporting processes of the Company, including the Company’s internal controls over financial reporting, and the audits of the consolidated financial statements of the Company.

During the course of 2015 and the first quarter of 2016, the audit committee met and held discussions with management and the independent auditors. In the discussions related to the Company’s consolidated financial statements for fiscal year 2015, management represented to the audit committee that such consolidated financial statements were prepared in accordance with United States generally accepted accounting principles. The audit committee reviewed and discussed with management and the independent auditors the audited consolidated financial statements for fiscal year 2015.

In fulfilling its responsibilities, the audit committee discussed with the independent auditors the matters that are required to be discussed by PCAOB Auditing Standards No. 16, *Communication with Audit Committees*. In addition, the audit committee received from the independent auditors the written disclosures and letter required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent auditor's communications with the audit committee concerning independence, and the audit committee discussed with the independent auditors that firm’s independence. In connection with this discussion, the audit committee also considered whether the provision of services by the independent auditors not related to the audit of the Company’s financial statements for fiscal year 2015 were compatible with maintaining the independent auditors’ independence. The audit committee’s policy requires that the audit committee approve any audit or permitted non-audit service proposed to be performed by its independent auditors in advance of the performance of such service.

Based upon the audit committee’s discussions with management and the independent auditors and the audit committee's review of the representations of management and the written disclosures and letter of the independent auditors provided to the audit committee, the audit committee recommended to the board of directors that the audited consolidated financial statements for the year ended December 31, 2015 be included in the Company’s Annual Report on Form 10-K, for filing with the SEC.

The Audit Committee

Kevin A. Richardson, II (Chair)
John F. Nemelka
Alan L. Rubino

March 30, 2016

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. All financial statements

The following financial statements are included in this Annual Report on Form 10-K and incorporated herein by reference:

2. Financial statement schedules

No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

3. Exhibits

The exhibits listed on the accompanying Exhibit Index are furnished or filed and, as applicable, are incorporated by reference herein as part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned hereunto duly authorized.

SANUWAVE HEALTH, INC.

Dated: March 30, 2016

By: */s/ Kevin A. Richardson, II*
Name: Kevin A. Richardson, II
Title: Acting Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signatures	**Capacity**	**Date**
By: /s/ *Kevin A. Richardson, II* Name: Kevin A. Richardson, II	Acting Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	March 30, 2016
By: /s/ *Lisa E. Sundstrom* Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	March 30, 2016
By: /s/ *John F. Nemelka* Name: John F. Nemelka	Director	March 30, 2016
By: /s/ *Alan L. Rubino* Name: Alan L. Rubino	Director	March 30, 2016

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).
3.4	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
3.6*	Certificate of Amendment to the Articles of Incorporation, dated September 8, 2015.
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock of the Company dated January 12, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
4.1	Form of Class A Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.2	Form of Class B Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

4.3	Form of Class D Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on October 14, 2010).
4.4	Form of Class E Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).
4.5	Form of Series A Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.6	Form of Series B Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.7	Form of 18% Senior Secured Convertible Promissory Note issued by SANUWAVE Health, Inc. to select accredited investors (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).
4.8	Form of Convertible Promissory Note between the Company and accredited investors party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.9	Amendment No. 1 to the Convertible Note Agreement between the Company and accredited investors party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).

4.10	Class K Warrant Agreement by and between the Company and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015).
4.11	Form of Class L Warrant Common Stock Purchase Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 17, 2016).
10.1	Amended and Restated 2006 Stock Option Incentive Plan of SANUWAVE Health, Inc. (Incorporated by reference to Form 8-K filed with the SEC on November 3, 2010).
10.2	Form of Securities Purchase Agreement, by and among the Company and the accredited investors party thereto, dated March 17, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
10.3	Form of Registration Rights Agreement, by and among the Company and the holders party thereto, dated March 17, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
10.4	Form of Subscription Agreement for the 18% Convertible Promissory Notes between the Company and the accredited investors a party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
10.5	Amendment to certain Promissory Notes that were dated August 1, 2005, by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015.)
10.6	Security Agreement, by and between the Company and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015).
14.1*	Code of Business Conduct and Ethics of SANUWAVE Health, Inc.
21.1*	List of subsidiaries
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Chief Executive Officer.

32.2*	Section 1350 Certification of the Chief Financial Officer.
101.INS**	XBRL Instance
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation
101.DEF**	XBRL Taxonomy Extension Definition
101.LAB**	XBRL Taxonomy Extension Labels
101.PRE**	XBRL Taxonomy Extension Presentation

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* Filed herewith

** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

SANUWAVE Health, Inc. and Subsidiaries

Alpharetta, Georgia

We have audited the accompanying consolidated balance sheets of SANUWAVE Health, Inc. and Subsidiaries as of December 31, 2015 and 2014 and the related consolidated statements of comprehensive loss, stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of SANUWAVE Health, Inc. and Subsidiaries at December 31, 2015 and 2014, and the results of their operations and their cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note (1) to the consolidated financial statements, the Company has suffered recurring losses from operations and is dependent upon future issuances of equity or other financing to fund ongoing operations, both of which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are described in Note (1). The consolidated financial statements do not include any

adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Atlanta, Georgia

March 30, 2016

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2015 and 2014

	2015	2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$152,930	$3,547,071
Accounts receivable, net of allowance for doubtful accounts of $8,963 in 2015 and $15,018 in 2014	74,454	86,404
Inventory, net (Note 3)	284,908	271,871
Prepaid expenses	123,988	128,550
TOTAL CURRENT ASSETS	636,280	4,033,896
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation	4,228	7,840
OTHER ASSETS	11,097	11,106
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 4)	306,756	613,513
TOTAL ASSETS	$958,361	$4,666,355
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$509,266	$231,840
Accrued expenses (Note 5)	359,374	369,456
Accrued employee compensation	241,542	2,226
Interest payable, related parties (Note 6)	239,803	81,864
Notes payable, related parties (Note 6)	-	5,372,743
Warrant liability (Note 2)	138,100	159,626
TOTAL CURRENT LIABILITIES	1,488,085	6,217,755
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 6)	5,348,112	-
TOTAL LIABILITIES	6,836,197	6,217,755
COMMITMENTS AND CONTINGENCIES (Note 11)		
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 at December 31, 2015 and 2014, respectively (Note 9)	-	1

PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,825 shares authorized; no shares issued and outstanding (Note 9)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 63,056,519 issued and outstanding at December 31, 2015; 150,000,000 shares authorized; 60,726,519 issued and outstanding at December 31, 2014 (Note 8)	63,057	60,727
ADDITIONAL PAID-IN CAPITAL	87,086,677	86,584,472
ACCUMULATED DEFICIT	(92,994,408)	(88,184,123)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(33,162)	(12,477)
TOTAL STOCKHOLDERS' DEFICIT	(5,877,836)	(1,551,400)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$958,361	$4,666,355

The accompanying notes to consolidated financial statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Years Ended December 31, 2015 and 2014

	2015	2014
REVENUES	$965,501	$847,367
COST OF REVENUES	284,962	219,975
GROSS PROFIT	680,539	627,392
OPERATING EXPENSES		
Research and development	2,172,819	3,000,807
General and administrative	2,735,129	3,269,033
Depreciation	3,612	14,286
Amortization	306,757	306,756
Gain on sale of assets	(100,000)	-
TOTAL OPERATING EXPENSES	5,118,317	6,590,882
OPERATING LOSS	(4,437,778)	(5,963,490)
OTHER (INCOME) EXPENSE		
Gain on warrant valuation adjustment (Note 2)	58,515	458,857
Interest expense, net	(399,832)	(433,775)
Amortization of debt discount	(12,358)	-
Interest expense on 18% Convertible Promissory Notes (Note 9)	-	(7,168)
Accretion of debt discount on convertible promissory note (Note 9)	-	(12,776)
Loss on foreign currency exchange	(18,832)	(15,728)
TOTAL OTHER EXPENSE	(372,507)	(10,590)
NET LOSS	(4,810,285)	(5,974,080)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(20,685)	(19,165)
TOTAL COMPREHENSIVE LOSS	$(4,830,970)	$(5,993,245)
LOSS PER SHARE:		
Net loss - basic and diluted	$(0.08)	$(0.12)
Weighted average shares outstanding - basic and diluted	63,025,202	48,212,910

The accompanying notes to consolidated financial statements are an integral part of these statements.

F-3

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

Years Ended December 31, 2015 and 2014

	Preferred Stock, Series A Convertible		Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balances as of December 31, 2013	-	$ -	37,984,182	$37,984	$76,037,490	$(82,210,043)	$ 6,688	$(6,127,881)
Net loss	-	-	-	-	-	(5,974,080)	-	(5,974,080)
Shares issued in 2014 Private Placement	6,175	6	6,210,000	6,210	7,998,551	-	-	8,004,767
Shares issued in 18% Convertible Promissory Notes conversion	-	-	1,644,337	1,645	772,549	-	-	774,194
Preferred stock conversion to common stock	(5,010)	(5)	10,020,000	10,020	(10,015)	-	-	-
Shares issued in related party subscription agreement	-	-	3,600,000	3,600	896,400	-	-	900,000
Shares issued for services	-	-	1,208,000	1,208	741,942	-	-	743,150
Shares issued for stock option exercise	-	-	60,000	60	12,540	-	-	12,600
Stock-based compensation -	-	-	-	-	135,015	-	-	135,015

options								
Foreign currency translation adjustment	-	-	-	-	-	-	(19,165)	(19,165)
Balances as of December 31, 2014	1,165	1	60,726,519	60,727	86,584,472	(88,184,123)	(12,477)	(1,551,400)
Net loss	-	-	-	-	-	(4,810,285)	-	(4,810,285)
Preferred stock conversion to common stock	(1,165)	(1)	2,330,000	2,330	(2,329)	-	-	-
Stock-based compensation - options	-	-	-	-	504,534	-	-	504,534
Foreign currency translation adjustment	-	-	-	-	-	-	(20,685)	(20,685)
Balances as of December 31, 2015	-	$ -	63,056,519	$63,057	$87,086,677	$(92,994,408)	$ (33,162)	$(5,877,836)

The accompanying notes to consolidated financial statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended December 31, 2015 and 2014

	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(4,810,285)	$(5,974,080)
Adjustments to reconcile loss from continuing operations to net cash used by operating activities		
Amortization	306,757	306,756
Depreciation	3,612	14,286
Change in allowance for doubtful accounts	(6,055)	(28,264)
Stock-based compensation - employees, directors and advisors	504,534	135,015
Stock issued for consulting services	-	743,150
Gain on sale of assets	(100,000)	-
Gain on warrant valuation adjustment	(58,515)	(458,857)
Amortization of debt discount	12,358	-
Accretion of debt discount on a convertible promissory note	-	12,776
Accrued interest on 18% Convertible Promissory Notes	-	7,168
Changes in assets - (increase)/decrease		
Accounts receivable - trade	18,005	81,596
Inventory	(13,037)	(25,865)
Prepaid expenses	4,562	(53,530)
Other	9	338
Changes in liabilities - increase/(decrease)		
Accounts payable	277,426	(703,188)
Accrued expenses	(10,082)	(494,116)
Accrued employee compensation	239,316	(137,876)
Interest payable, related parties	157,939	(81,865)
Promissory notes - accrued interest	-	(21,813)
NET CASH USED BY OPERATING ACTIVITIES	(3,473,456)	(6,678,369)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of assets	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	(20,685)	(19,165)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,394,141)	3,364,756
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,547,071	182,315
CASH AND CASH EQUIVALENTS, END OF YEAR	$152,930	$3,547,071
SUPPLEMENTAL INFORMATION		
Cash paid for interest	$242,904	$539,669

The accompanying notes to consolidated financial statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

1. Going Concern

As shown in the accompanying consolidated financial statements, SANUWAVE Health, Inc. and subsidiaries (the "Company") incurred a net loss of $4,810,285 and $5,974,080 during the years ended December 31, 2015 and 2014, respectively, and the net cash used by operating activities was $3,473,456 and $6,678,369, respectively. As of December 31, 2015, the Company had a net working capital deficit of $851,805, total stockholders' deficit of $5,877,836 and cash and cash equivalents of $152,930. These factors create an uncertainty about the Company's ability to continue as a going concern.

The Company does not currently generate significant recurring revenue and will require additional capital during or before the third quarter of 2016. Although no assurances can be given, management of the Company believes that existing capital resources should enable the Company to fund operations into the third quarter of 2016.

The continuation of the Company's business is dependent upon raising additional capital during or before the third quarter of 2016 to fund operations. Management's plans are to obtain additional capital in 2016 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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 consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

2. Summary of significant accounting policies

Description of the business – SANUWAVE Health, Inc. and subsidiaries (the "Company") is an acoustic pressure shock wave technology company using a patented system of noninvasive, high-energy, acoustic pressure shock waves for indications such as regenerative medicine and other applications. The Company's initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the

body healing itself through the repair and regeneration of skin, musculoskeletal tissue, 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 with possible FDA approval in 2016.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

The significant accounting policies followed by the Company are summarized below:

Foreign currency translation - The functional currencies of the Company's foreign operations are the local currencies. The financial statements of the Company's foreign subsidiary have been translated into United States dollars in accordance with ASC 830, *Foreign Currency Matters*, Foreign Currency Translation. All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. Translation adjustments are reported in other comprehensive income (loss) in the consolidated statements of comprehensive loss and as cumulative translation adjustments in accumulated other comprehensive income (loss) in the consolidated statements of stockholders' deficit.

Principles of consolidation - The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Estimates – These consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. Because a precise determination of assets and liabilities, and correspondingly revenues and expenses, depend on future events, the preparation of consolidated financial statements for any period necessarily involves the use of estimates and assumptions. Actual amounts may differ from these estimates. These consolidated financial statements have, in management's opinion, been properly prepared within reasonable limits of materiality and within the framework of the accounting policies summarized herein. Significant estimates include the recording of allowances for doubtful accounts, estimated reserves for inventory, valuation of derivatives, accrued expenses, the determination of the valuation allowances for deferred taxes, estimated fair value of stock-based compensation and the estimated fair value of intangible assets.

Cash and cash equivalents - For purposes of the consolidated financial statements, liquid instruments with an original maturity of 90 days or less are considered cash and cash equivalents. The Company maintains its cash in bank accounts which may exceed federally insured limits.

Concentration of credit risk and limited suppliers - Management routinely assesses the financial strength of its customers and, as a consequence, believes accounts receivable are stated at the net realizable value and credit risk exposure is limited. Two distributors accounted for 37% and 29% of revenues for the year ended December 31, 2015, and 63% and 10% of accounts receivable at December 31, 2015. Two distributors accounted for 26% and 34% of revenues for the year ended December 31, 2014, and 24% and 34% of accounts receivable at December 31, 2014.

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. 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

Accounts receivable - Accounts receivable are stated at the amount management expects to collect from outstanding balances. Management provides for probable uncollectible amounts through a charge to earnings based on its assessment of the current status of individual accounts. Receivables are generally considered past due if greater than 60 days old. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the allowance for doubtful accounts.

Inventory - Inventory consists of finished medical equipment and parts and is stated at the lower of cost or market, which is valued using the first in, first out ("FIFO") method. Market is based upon realizable value less allowance for selling and distribution expenses. The Company analyzes its inventory levels and writes down inventory that has, or is expected to, become obsolete.

Intangible assets - Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over 11.4 years. The Company regularly reviews intangible assets to determine if facts and circumstances indicate that the useful life is shorter than the Company originally estimated or that the carrying amount of the assets may not be recoverable. Factors the Company considers important and could trigger an impairment review include the following:

- Significant delays or obstacles encountered in the dermaPACE device clinical trial and PMA application;
- Significant changes in the manner in which the Company uses its assets or significant changes in the Company's overall business strategy; and
- Significant underperformance of the Company's assets relative to future operating results.

If such facts and circumstances exist, the Company assesses 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 its fair value.

Fair value of financial instruments - The book values of accounts receivable, accounts payable, and other financial instruments approximate their fair values, principally because of the short-term maturities of these instruments.

The Company has adopted ASC 820-10, *Fair Value Measurements* , which defines fair value, establishes a framework for measuring fair value and requires disclosures about fair value measurements. The framework that is set forth in this standard is applicable to the fair value measurements where it is permitted or required under other accounting pronouncements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

The ASC 820-10 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 - Unobservable inputs that are not corroborated by market data, therefore requiring the Company to develop its own assumptions.

The following table sets forth a summary of changes in the fair value of the derivative liability for the year ended December 31, 2015:

	Warrant Liability
Balance at December 31, 2014	$159,626
New issuances	36,989
Change in fair value	(58,515)
Balance at December 31, 2015	$138,100

The Company accounts for derivative instruments under ASC 815, *Accounting for Derivative Instruments and Hedging Activities*, as amended and interpreted. ASC 815 requires that the Company recognize all derivatives on the balance sheet at fair value. The fair value of the warrant liability is determined based on a lattice solution, binomial

approach pricing model, and includes the use of unobservable inputs such as the expected term, anticipated volatility and risk-free interest rate, and therefore is classified within level 3 of the fair value hierarchy.

The Company's notes payable, related parties had an aggregate outstanding principal balance of $5,348,112, net of $24,631 debt discount at December 31, 2015 and $5,372,743 at December 31, 2014, respectively. Interest accrues on the notes at a rate of eight percent per annum, effective June 15, 2015. The fair value was determined using estimated future cash flows discounted at current rates, which is a Level 3 measurement. The estimated fair value of the Company's notes payable, related parties was $4,844,792 and $5,221,985 at December 31, 2015 and 2014, respectively.

Impairment of long-lived assets – The Company reviews long-lived assets for impairment whenever facts and circumstances indicate that the carrying amounts of the assets may not be recoverable. An impairment loss is recognized only if the carrying amount of the asset is not recoverable and exceeds its fair value. Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the asset's carrying value is not recoverable, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds its fair value. The Company determines fair value by using a combination of comparable market values and discounted cash flows, as appropriate.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

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. The Company recognizes revenues on shipments to distributors in the same manner as with other customers. Fees from services performed are recognized when the service is performed.

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs have been recorded in cost of revenues.

Income taxes - Income taxes are accounted for utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes*, 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.

A provision of ASC 740, *Income Taxes*, Accounting for Uncertainty in Income Taxes (FIN 48) 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 the Company’s 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.

The Company will recognize in income tax expense interest and penalties related to income tax matters. For the years ended December 31, 2015 and 2014, the Company did not have any amounts recorded for interest and penalties.

Loss per share - The Company calculates net income (loss) per share in accordance with ASC 260, *Earnings Per Share*. Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. To the extent that securities are "anti-dilutive," they are excluded from the calculation of diluted net income (loss) per share. As a result of the net loss for the years ended December 31, 2015 and 2014, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive equity securities totaled 48,376,071 shares and 60,100,368 shares at December 31, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

Comprehensive income – ASC 220, *Comprehensive Income*, Reporting Comprehensive Income establishes standards for reporting comprehensive income (loss) and its components in a financial statement. Comprehensive income (loss) as defined includes all changes in equity (net assets) during a period from non-owner sources. The only source of other comprehensive income (loss) for the Company, which is excluded from net income (loss), is foreign currency translation adjustments.

Stock-based compensation - The Company uses the fair value method of accounting prescribed by ASC 718, *Compensation – Stock Compensation*, Accounting for Stock-Based Compensation for its employee stock option program. Under ASC 718, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the applicable vesting period of the stock award (generally up to three years).

Research and development - Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to the Company's 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.

Recent pronouncements – 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

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 August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU provides guidance on management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures in the notes to the financial statements. The amendments in this ASU should help reduce the diversity in the timing and content of disclosures in the notes to the financial statements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The implementation of this ASU is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In April 2015, the FASB issued ASU 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. This ASU provides guidance that simplifies the presentation of debt issuance costs by amending the accounting guidance to require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability. The

amendments are consistent with the accounting guidance related to debt discounts. This guidance is effective for the first interim or annual period beginning after December 15, 2015. The Company will adopt this guidance in the first quarter of fiscal 2016. The Company is currently assessing the impact of this guidance on its consolidated financial statements.

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.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. This ASU provides guidance that simplifies the presentation of deferred income taxes. This ASU requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The implementation of this ASU is not expected to have a material impact on the Company’s consolidated financial position or results of operations.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

2. Summary of significant accounting policies (continued)

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize the most leases on the balance sheet. The provisions of this guidance are effective for the annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. Management is evaluating the requirements of this guidance and has not yet determined the impact of the adoption on the Company's financial position or results of operations.

3. Inventory

Inventory consists of the following at December 31, 2015 and 2014:

	2015	2014
Inventory - finished goods	$290,623	$263,027
Inventory - parts	87,450	92,744
Gross inventory	378,073	355,771
Provision for losses and obsolescence	(93,165)	(83,900)
Net inventory	$284,908	$271,871

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

4. Intangible assets

Intangible assets consist of the following at December 31, 2015 and 2014:

	2015	2014
Patents, at cost	$3,502,135	$3,502,135
Less accumulated amortization	(3,195,379)	(2,888,622)
Net intangible assets	$306,756	$613,513

Amortization expense was $306,757 and $306,756 for the years ended December 31, 2015 and 2014, respectively. The amortization policies followed by the Company are described in Note 2.

Amortization expense for the future years is summarized as follows:

Years ending December 31,	Amount
2016	306,756
Total	$306,756

The weighted average amortization period for intangible assets is as follows:

Amount	Weighted Average

		Period (Years)
Patents	$3,502,135	11.4

5. Accrued expenses

Accrued expenses consist of the following at December 31, 2015 and 2014:

	2015	2014
Accrued executive severance	$100,000	$100,000
Accrued audit and tax preparation	93,500	55,500
Accrued legal professional fees	76,500	111,600
Accrued outside services	58,813	-
Accrued clinical study expenses	22,777	64,464
Accrued board of director's fees	-	12,000
Accrued other	7,784	25,892
	$359,374	$369,456

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

5. Accrued expenses (continued)

On November 6, 2012, the Company entered into a Severance and Advisory Agreement (the "Severance Agreement") with Christopher M. Cashman in connection with his resignation as President and Chief Executive Officer, and a director of the Company. Pursuant to the Severance Agreement, Mr. Cashman will receive, as severance along with other non-cash items, six months of his base salary payable over the following six month period and bonus payments of $100,000 upon each of four bonus payment events tied to the Company's clinical trial plan for the dermaPACE device, or December 31, 2016, whichever occurs first. The Company achieved three of the four bonus payment events in 2014 and paid $300,000 in accrued executive severance during the year ended December 31, 2014. The accrued executive severance at December 31, 2014 and 2015 represents the unpaid portion of the bonus payments.

6. 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 was paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal was due August 1, 2015.

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 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.

The notes payable, related parties had an aggregate outstanding principal balance of $5,348,112, net of $24,631 debt discount at December 31, 2015 and $5,372,743 at December 31, 2014, respectively.

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 $239,803 and $81,864 at December 31, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

6. Notes payable, related parties (continued)

Maturities on notes payable, related parties are as follows:

Years ending December 31,	Amount
2016	$-
2017	5,372,743
Total	$5,372,743

Interest expense on notes payable, related parties totaled $413,200 and $325,804 for the years ended December 31, 2015 and 2014, respectively.

7. 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 2007.

Deferred income taxes are provided for temporary differences between the carrying amounts and tax basis of assets and liabilities. Deferred taxes are classified as current or noncurrent based on the financial statement classification of the related asset or liability giving rise to the temporary difference. For those deferred tax assets or liabilities (such as the tax effect of the net operating loss carryforwards) which do not relate to a financial statement asset or liability, the classification is based on the expected reversal date of the temporary difference.

The income tax provision (benefit) from continuing operations consists of the following at December 31, 2015 and 2014:

	2015	2014
Current:		
Federal	$-	$-
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	(1,605,319)	(2,198,311)
State	(176,377)	(241,530)
Foreign	2,419	9,532
Deferred Tax True Up	1,803,402	-
Change in valuation allowance	(24,125)	2,430,309
	$-	$-

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

7. Income taxes (continued)

The income tax provision (benefit) amounts differ from the amounts computed by applying the United States federal statutory income tax rate of 35% to pretax income (loss) from continuing operations as a result of the following for the years ended December 31, 2015 and 2014:

	2015	2014
Tax expense (benefit) at statutory rate	$(1,683,600)	$(2,090,928)
Increase (reduction) in income taxes resulting from:		
State income taxes (benefit), net of federal benefit	(119,778)	(148,758)
Non-deductible gain on warrant valuation adjustment	(19,895)	(156,011)
Income from foreign subsidiaries	12,330	16,615
Deferred tax true up	1,803,402	-
Change in valuation allowance - United States	(24,125)	2,439,841
Other	31,666	(60,759)
Income tax expense (benefit)	$-	$-

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2015 and 2014 are as follows:

	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$26,451,449	$24,919,846
Net operating loss carryforwards - foreign	127,578	129,997
Excess of tax basis over book value of property and equipment	20,158	20,685
Excess of tax basis over book value of intangible assets	443,597	439,569
Stock-based compensation	1,834,172	3,447,183
Accrued employee compensation	90,442	37,736
Captialized equity costs	75,471	75,471
Inventory reserve	35,156	31,661
	29,078,023	29,102,148
Valuation allowance	(29,078,023)	(29,102,148)

Net deferred tax assets	$-	$-

During 2015, the Company undertook a detailed review of the Company's deferred taxes and it was determined that some reclassifications and adjustments were needed for stock-based compensation. All adjustments were offset by changes to the Company's valuation allowance and have been reflected in the 2015 year end balances noted above.

The Company’s ability to use its net operating loss 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 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, the Company may not be able to take advantage of all or portions of its net operating loss carryforwards for federal income tax purposes.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

7. Income taxes (continued)

The federal net operating loss carryforwards at December 31, 2015 will expire as follows:

Years ending December 31,	Amount
2025	$1,376,740
2026	7,291,084
2027	12,280,771
2028	6,922,963
2029	4,816,700
2030	7,667,557
2031	8,816,976
2032	4,768,716
2033	5,413,661
2034	6,663,638
2035	4,077,996
Total	$70,096,802

8. 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 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.

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 covers 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

8. Equity Transactions (continued)

Kevin A. Richardson, II, chairman of the board of directors of the Company and now 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.

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 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.

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 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

8. Equity Transactions (continued)

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.

$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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

8. Equity Transactions (continued)

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 "full ratchet" anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price.

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.

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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

8. Equity Transactions (continued)

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 1,005,000 shares of common stock under these agreements in February 2014 through May 2014. The fair value of the common stock of $624,150 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 for the year ended December 31, 2014.

9. 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 8).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

9. 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 January 6, 2015, there were no more outstanding shares of Series A Convertible Preferred Stock.

10. Warrants

A summary of warrants as of December 31, 2015 and 2014, and the changes during the years ended December 31, 2015 and 2014, is presented as follows:

Warrant class	Outstanding as of	Issued	Exercised	Expired	Outstanding as of	Issued	Exercised	Expired	Outstanding as of

	December 31, 2013				December 31, 2014				December 31, 2015
Class A Warrants	1,106,627	-	-	(1,106,627)	-	-	-	-	-
Class B Warrants	1,106,627	-	-	(1,106,627)	-	-	-	-	-
Class E Warrants	3,576,737	-	-	-	3,576,737	-	-	-	3,576,737
Class F Warrants	300,000	-	-	-	300,000	-	-	-	300,000
Class G Warrants	1,503,409	-	-	-	1,503,409	-	-	-	1,503,409
Class H Warrants	1,988,095	-	-	-	1,988,095	-	-	-	1,988,095
Class I Warrants	1,043,646	-	-	-	1,043,646	-	-	-	1,043,646
Class J Warrants	-	629,378	-	-	629,378	-	-	-	629,378
Class K Warrants	-	-	-	-	-	3,310,000	-	-	3,310,000
Series A Warrants	-	25,951,421	-	-	25,951,421	-	-	-	25,951,421
Series B Warrants	-	15,570,852	-	-	15,570,852	-	-	(15,570,852)	-
	10,625,141	42,151,651	-	(2,213,254)	50,563,538	3,310,000	-	(15,570,852)	38,302,686

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

10. Warrants (continued)

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

	Exercise price/share	Expiration date
Class A Warrants	$ 4.00	September 2014
Class B Warrants	$ 8.00	September 2014
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, the Series A Warrants and the Series B 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 and Series B Warrants may be exercised on a physical settlement basis if a registration statement underlying the warrants if 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 or Series B Warrants, then the holder may exercise the warrants on a cashless basis. The Series B Warrants expired in March 2015.

In February 2013, the Company issued 2,000,000 warrants to a consultant to purchase the Company's common stock at $0.35 per share (the "Class F Warrants"). The five year Class F Warrants vest 300,000 on the date of grant and 1,700,000 upon the completion of a $5,000,000, or greater, capital raise on or prior to June 8, 2013. A capital raise was not completed for the requisite amount and the 1,700,000 Class F Warrants expired by their terms. The Company recorded the underlying cost of the 300,000 Class F Warrants as a cost of the Public Offering.

In June 2015, the Company, in connection with the Note Amendment (Note 7), issued to HealthTronics, Inc. an aggregate total of 3,310,000 Class K Warrants to purchase shares of the Company's common stock, $0.001 par value, 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

10. Warrants (continued)

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 is 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. Prior to the fourth quarter of 2014, these warrants were not treated as derivative financial instruments and recorded at fair value. Accordingly, during the fourth quarter 2014, we recorded an adjustment to reduce interest expense by $327,088 and reflect a gain on the fair value adjustment for the warrants of $458,857 to reflect the annual activity for these instruments. The amounts were not significant to any of the previously reported quarterly condensed consolidated financial statements. 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 and the volatility of the Company’s common stock price.

11. Commitments and contingencies

Operating Leases

The Company leases office and storage space. Rent expense for the years ended December 31, 2015 and 2014, was $155,926 and $132,814, respectively. The Company amended the lease on November 1, 2015 to remain in the current space on a month-to-month basis.

Litigation

The Company is involved in various legal matters that have arisen in the ordinary course of business. While the ultimate outcome of these matters is not presently determinable, it is the opinion of management that the resolution will not have a material adverse effect on the financial position or results of operations of the Company.

12. Stock-based compensation

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 non-statutory 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 non-statutory options which generally vest over a period of up to three years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At December 31, 2015 and 2014 the Stock Incentive Plan reserved a total of 12,500,000 and 8,500,000, respectively, shares of common stock for grant.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

12. Stock-based compensation (continued)

On October 1, 2015, the Company granted to the active employees and members of the board of directors options to purchase 1,900,000 shares of common stock at an exercise price of $0.11 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.11 resulting in compensation expense of $209,000. Compensation cost was recognized upon grant.

On October 1, 2015, the Company granted to the active employees, members of the board of directors and members of the Medical Advisory Board options to purchase 1,450,000 shares of common stock an exercise price of $0.50 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.10 resulting in compensation expense of $145,000. Compensation cost was recognized upon grant.

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. A part of the settlement was the issuance of stock options. Using the Black-Scholes option pricing model, management has determined that the options had a fair value resulting in compensation expense of $98,100. Compensation cost was recognized upon grant.

On April 28, 2015, the Company granted two members of the Company’s Medical Advisory Board each options to purchase 50,000 shares of the Company’s common stock at an exercise price of $0.55 per share in place of an annual cash consulting fee for calendar year 2015. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.11 resulting in compensation expense of $11,107. Compensation cost was recognized over the requisite service period in calendar year 2015.

On September 4, 2014, the Company granted two members of the Company’s Medical Advisory Board each options to purchase 75,000 shares of the Company’s common stock at an exercise price of $0.55 per share in place of an annual cash consulting fee for calendar year 2014. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.24 resulting in compensation expense of $35,625.

Compensation cost was recognized over the requisite service period in calendar year 2014.

On May 7, 2014, the Company granted to the active employees options to purchase 900,000 shares of common stock at an exercise price of $0.55 per share. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.48 resulting in compensation expense of $429,001. Compensation cost is being recognized over the requisite service period.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

12. Stock-based compensation (continued)

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the years ended December 31, 2015 and 2014:

	2015		2014	
Weighted average expected life in years	5.0		5.4	
Weighted average risk free interest rate	1.42	%	1.81	%
Weighted average volatility	120.63	%	136.11	%
Forfeiture rate	0.0	%	0.0	%
Expected dividend yield	0.0	%	0.0	%

The expected life of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted. The risk-free rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of the grant. Since there is a limited trading history for our common stock, the expected volatility is based on historical data from companies similar in size and value to us. We estimate pre-vesting forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The expected dividend yield is based on our historical dividend experience, however, since our inception, we have not declared dividends. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest.

For the years ended December 31, 2015 and 2014, the Company recognized $504,534 and $135,015, respectively, as compensation cost related to options granted. The remaining compensation cost will be recognized as follows:

Years ending December 31,	Unrecognized Compensation Cost

2016	$ 6,000
Total	$ 6,000

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

12. Stock-based compensation (continued)

A summary of option activity as of December 31, 2015 and 2014, and the changes during the years ended December 31, 2015 and 2014, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding at December 31, 2013	8,366,830	$ 1.17
Granted	1,050,000	$ 0.55
Exercised	(60,000)	$ 0.21
Cancelled	-	$ -
Forfeited or expired	(2,150,000)	$ 0.41
Outstanding at December 31, 2014	7,206,830	$ 1.31
Granted	4,950,000	$ 0.35
Exercised	-	$ -
Cancelled	-	$ -
Forfeited or expired	(2,083,445)	$ 2.39
Outstanding at December 31, 2015	10,073,385	$ 0.62
Vested and exercisable at December 31, 2015	9,898,383	$ 0.62

The range of exercise prices for options was $0.11 to $2.00 for options outstanding at December 31, 2015 and 2014. The aggregate intrinsic value for outstanding options was $0 at December 31, 2015 and 2014. The aggregate intrinsic value for all vested and exercisable options was $0 at December 31, 2015 and 2014.

The weighted average remaining contractual term for outstanding exercisable stock options is 7.46 years and 6.43 years as of December 31, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

12. Stock-based compensation (continued)

A summary of the Company's nonvested options as of December 31, 2015 and 2014, and changes during the years ended December 31, 2015 and 2014, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding at December 31, 2013	3,254,092	$ 0.35
Granted	1,050,000	$ 0.55
Vested	(1,464,551)	$ 0.41
Cancelled	-	$ -
Forfeited or expired	(1,924,999)	$ 0.39
Outstanding at December 31, 2014	914,542	$ 0.37
Granted	4,950,000	$ 0.35
Vested	(5,672,874)	$ 0.36
Cancelled	-	$ -
Forfeited or expired	(16,666)	$ 0.55
Outstanding at December 31, 2015	175,002	$ 0.36

13. Changes in other comprehensive income (loss)

A summary of the amounts recognized in other comprehensive income (loss) as of December 31, 2015 and 2014, and changes during the years then ended, is presented as follows:

	Currency Translations	Total
Balance, at December 31, 2013	$ 6,688	$6,688
Net change in other comprehensive loss	(19,165)	(19,165)

Balance, at December 31, 2014	(12,477)	(12,477)
Net change in other comprehensive loss	(20,685)	(20,685)
Balance, at December 31, 2015	$ (33,162)	$(33,162)

14. Segment and geographic information

The Company has one line of business with revenues being generated from sales in Europe, Canada, Asia and Asia/Pacific. All significant expenses are generated in the United States. All significant assets are located in the United States.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

15. Subsequent events

2016 Equity Offering

On March 11, 2016, in conjunction with an equity offering of securities (the "2016 Equity Offering") with select accredited investors, the Company issued an aggregate of 25,495,835 shares of common stock for an aggregate purchase price of $1,529,750. The mandatory prepayment of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company has been waived by HealthTronics, Inc. for this 2016 Equity Offering.

The Company, in connection with the 2016 Equity Offering, issued to the investors an aggregate of 25,495,835 warrants (the "Class L Warrants") to purchase shares of common stock at an exercise price of $0.08 per share. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019.

Pursuant to the terms of a Registration Rights Agreement that the Company entered with the investors in connection with the 2016 Equity Offering, the Company is required to file a registration statement that covers the shares of common stock and the shares of common stock issuable upon exercise of the Class L Warrants. The failure on the part of the Company to satisfy certain deadlines described in the Registration Rights Agreement may subject the Company to payment of certain monetary penalties.

Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Equity Offering of $100,000.

$58,300 Convertible Promissory Notes and Warrants

On February 1, 2016, the Company entered into a financing transaction for the sale of an 8% Convertible Promissory Note (the "$58,300 Convertible Note") and warrants (the "Class M Warrants") in the principal amount of $58,300 each, with gross proceeds of $50,000 to the Company after payment of a 10% original issue discount and related professional expenses. The offering was conducted pursuant to the exemption from registration provided by Section 4(a)(2) of the Act and Rule 506 of Regulation D thereunder. The Company did not utilize any form of general solicitation or general advertising in connection with the offering. The $58,300 Convertible Note was offered and sold to two accredited investors.

The $58,300 Convertible Note and Class M Warrants were issued pursuant to the terms of a purchase agreement among the Company and the Investors. The convertible note is an unsecured obligation of the Company and, unless earlier redeemed, matures on August 1, 2016. The Company has the right to prepay the convertible note and accrued interest during the first sixty (60) days following the date of issuance. During that time, the amount of any prepayment during the first sixty (60) days is 120% of the outstanding amounts owed, and the amount of the prepayment increases every subsequent thirty (30) days. Each Class M Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire February 21, 2021.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

15. Subsequent events (continued)

The $58,300 Convertible Note is convertible, at any time from the issuance date, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 30% of the lowest reported sale price of the Company's common stock for the 20 trading days immediately prior to (i) the date of the purchase agreement or (ii) the voluntary conversion date. The Company is evaluating the accounting for the Convertible Note.

Series A Warrant Conversion

On January 13, 2016, the Company entered into an Exchange Agreement (the "Exchange Agreement") with certain beneficial owners (the "Investors") of Series A warrants (the "Warrants") to purchase shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), pursuant to which the Investors exchanged (the "Exchange") all of their respective Warrants for either (i) shares of Common Stock or (ii) shares of Common Stock and shares of the Company's Series B Convertible Preferred Stock, $0.001 par value (the "Preferred Stock").

The Exchange was based on the following exchange ratio (the "Exchange Ratio"): 1 Series A Warrant = 0.4685 shares of capital stock. Investors who, as a result of the Exchange, owned in excess of 9.99% (the "Ownership Threshold") of the outstanding Common Stock, received a mixture of Common Stock and shares of Preferred Stock. They received Common Stock up to the Ownership Threshold, and received shares of Preferred Stock beyond the Ownership Threshold (but the total shares of Common Stock and Preferred Stock issued to such holders was still based on the same Exchange Ratio). The relative rights, preferences, privileges and limitations of the Preferred Stock are as set forth in the Company's Certificate of Designation of Series B Convertible Preferred Stock, which was filed with the Secretary of State of the State of Nevada on January 12, 2016 (the "Series B Certificate of Designation").

In the Exchange an aggregate number of 23,701,428 Warrants were exchanged for 7,447,954 shares of Common Stock and 293 shares of Preferred Stock. Pursuant to the Series B Certificate of Designation, each of the Preferred Stock shares is convertible into shares of Common Stock at an initial rate of 1 Preferred Stock share for 12,500 Common Stock shares, which conversion rate is subject to further adjustment as set forth in the Series B Certificate of Designation. Pursuant to the terms of the Series B Certificate of Designation, the holders of the Preferred Stock shares will generally be entitled to that number of votes as is equal to the number of shares of Common Stock into which the Preferred Stock may be converted as of the record date of such vote or consent, subject to the Beneficial Ownership

Limitation.

In connection with entering into the Exchange Agreement, the Company also entered into a Registration Rights Agreement, dated January 13, 2016, with the Investors. The Registration Rights Agreement requires that the Company file with the SEC a registration statement to register for resale the shares of the Common Stock issued in connection with the Exchange and the Common Stock issuable upon conversion of the Preferred Stock shares (the “Preferred Stock Conversion Shares”).