SANUWAVE Health, Inc.
Form 10-K
April 01, 2019

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, 2018

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 (State or other jurisdiction of incorporation or organization)	20-1176000 (I.R.S. Employer Identification No.)
3360 Martin Farm Road, Suite 100 Suwanee, GA (Address of principal executive offices)	30024 (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 every Interactive Data File required to be submitted 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 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was $63.4 million.

As of March 28, 2019, there were issued and outstanding 160,322,580 shares of the registrant's common stock.

SANUWAVE Health, Inc.

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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, the Company’s near term cash requirements and cash sources, 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,” “es “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 a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies and was cleared by the U.S. Food and Drug Administration (FDA) on December 28, 2017.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. In 2018, we started marketing our dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

Our lead product candidate for the global wound care market, dermaPACE, has received FDA clearance for commercial use to treat diabetic foot ulcers in the United States and the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. We believe we have demonstrated that our patented technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our orthoPACE®, OssaTron, and Evotron® devices in Europe and Asia.

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

wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;

orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;

plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and

cardiac applications for removing plaque due to atherosclerosis improving heart muscle performance.

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 and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

We were formed as a Nevada corporation in 2004. We maintain a public internet site at www.sanuwave.com. The information on our websites is not part of this Annual Report on Form 10-K.

Pulsed Acoustic Cellular Expression (PACE) Technology for Regenerative Medicine

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

High-energy, acoustic pressure 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. We anticipate that future clinical studies should lead to regulatory approval of our regenerative product candidates in the Americas, Middle East and Africa. 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 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 system was evaluated using two studies under IDE G070103. The studies were designed as prospective, randomized, double-blind, parallel-group, sham-controlled, multi-center 24-week studies at 39 centers. A total of 336 subjects were enrolled and treated with either dermaPACE plus conventional therapy or conventional therapy (a.k.a. standard of care) alone. Conventional therapy included, but was not limited to, debridement, saline-moistened gauze, and pressure reducing footwear. The objective of the studies was to compare the safety and efficacy of the dermaPACE device to sham-control application. The prospectively defined primary efficacy endpoint for the dermaPACE studies was the incidence of complete wound closure at 12 weeks post-initial application of the dermaPACE system (active or sham). Complete wound closure was defined as skin re-epithelialization without drainage or dressing requirements, confirmed over two consecutive visits within 12-weeks. If the wound was considered closed for the first time at the 12 week visit, then the next visit was used to confirm closure. Investigators continued to follow subjects and evaluate wound closure through 24 weeks.

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 patient enrollment for the second, supplemental clinical trial began in June 2013. We completed enrollment for the 130 patients in this second trial in November 2014 and suspended further enrollment at that time.

The only significant difference between the two studies was the number of applications of the dermaPACE device. Study one (DERM01; n=206) prescribed four (4) device applications/treatments over a two-week period, whereas, study two (DERM02; n=130) prescribed up to eight (8) device applications (4 within the first two weeks of randomization, and 1 treatment every two weeks thereafter up to a total of 8 treatments over a 10-week period). If the wound was determined closed by the PI during the treatment regimen, any further planned applications were not performed.

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm2 and 16cm2, inclusive. Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 – Day 0), the first treatment was applied (either dermaPACE or Sham Control application). Applications with either dermaPACE or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

A total of 336 patients were enrolled in the dermaPACE studies at 37 sites. The patients in the studies were followed for a total of 24 weeks. The studies' primary endpoint, wound closure, was defined as "successful" if the skin was 100% re-epithelialized 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, 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=0.320). There were 39 out of 172 (22.67%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 30 out of 164 (18.29%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, and in conjunction with the FDA agreement to analyze the efficacy analysis carried over the full 24 weeks of the study, 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 61 (35.47%) dermaPACE subjects achieving complete wound closure compared with 40 (24.39%) of sham-control subjects (p=0.027). At the 24 week endpoint, the rate of wound closure in the dermaPACE® cohort was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023.

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 ($p<0.05$).

The proportion of patients with wound closure indicate a statistically significant difference between the dermaPACE and the control group in the proportion of subjects with the target-ulcer not closed over the course of the study (p-value=0.0346). Approximately 25% of dermaPACE® subjects reached wound closure per the study definition by day 84 (week 12). The same percentage in the control group (25%) did not reach wound closure until day 112 (week 16). These data indicate that in addition to the proportion of subjects reaching wound closure being higher in the dermaPACE® group, subjects are also reaching wound closure at a faster rate when dermaPACE is applied.

dermaPACE demonstrated superior results in the prevention of wound expansion (≥ 10% increase in wound size), when compared to the control, over the course of the study at 12 weeks (18.0% versus 31.1%; p=0.005, respectively).

At 12 and 24 weeks, the dermaPACE group had a higher percentage of subjects with a 50% wound reduction compared to the control (p=0.0554 and p=0.0899, respectively). Both time points demonstrate a trend towards

statistical significance.

The mean wound reduction for dermaPACE subjects at 24 weeks was 2.10cm2 compared to 0.83cm2 in the control group. There was a statistically significant difference between the wound area reductions of the two cohorts from the 6 week follow-up visit through the end of the study.

Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 7.7% in the dermaPACE group compared with 11.6% 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 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.

Working with MCRA, we submitted to FDA a de novo petition on July 23, 2016. Due to the strong safety profile of our device and the efficacy of the data showing statistical significance for wound closure for dermaPACE subjects at 20 weeks, we believe that the dermaPACE device should be considered for classification into Class II as there is no legally marketed predicate device and there is not an existing Class III classification regulation or one or more approved PMAs (which would have required a reclassification under Section 513(e) or (f)(3) of the FD&C Act). On December 28, 2017, the FDA determined that the criteria at section 513(a)(1)(A) of (B) of the FD&C Act were met and granted the de novo clearance classifying dermaPACE as Class II and available to be marketed immediately.

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, New Zealand and South Korea.

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

Clinical Studies

A dosage study has been developed for launch in Poland to optimize dermaPACE system treatment dosage for producing a more rapid reduction in size of a diabetic foot ulcer ("DFU"). The focus will be on increasing the number of shock waves delivered per treatment, as a function of DFUs area. To determine the dosage necessary, three new distinctive regimens will be assessed during the study. This study is expected to start in April 2019 and to be finalized late in the third quarter of 2019.

A post-market pilot study to evaluate the effects of high energy acoustic shock wave therapy on local skin perfusion and healing of DFUs will be conducted at two sites: one in New Jersey and one in California. The intent of this trial is to quantify the level of increased perfusion and oxygenation during and after treatment with the dermaPACE system. Enrollment and first patient treatment is expected in April 2019.

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Our FDA approval in the United States for our lead product candidate, dermaPACE, is the first step in providing an option to a currently unmet need in the treatment of diabetic foot ulcers. Diabetes is common, disabling and deadly. In the United States, diabetes has reached epidemic proportions. Based on our research, foot ulcerations are one of the leading causes of hospitalization in diabetic patients and lead to billions of dollars in health care expenditures annually. According to a 2015 report by the Centers for Disease Control and Prevention, approximately 30.3 million people (diagnosed and undiagnosed), roughly 9.4% of the United States population, have diabetes and 1.5 million new cases of diabetes were diagnosed in people aged 18 years or older in 2015. According to the same study, approximately 25% of diabetics will develop a DFU during their lifetime. Foot ulcers are a significant complication of diabetes mellitus and often precede lower-extremity amputation. The most frequent underlying etiologies are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease. Over 50% of DFUs will become infected, resulting in high rates of hospitalization, increased morbidity and potential lower extremity amputation. Diabetic foot infections ("DFI") are one of the most common diabetes related cause of hospitalization in the United States, accounting for 20% of all hospital admissions. Readmission rates for DFI patients are approximately 40% and

nearly one in six patients die within 1 year of their infection. In a large prospective study of patients with DFU, the presence of infection increased the risk of a minor amputation by 50% compared to ulcer patients without infection. DFUs account for more than half of the non-traumatic lower-extremity amputations in the world. In June 2006, Advanced Medical Technology Association ("AdvaMed") estimated that chronic leg wounds (ulcers) account for the loss of many workdays per year, at a cost of approximately $20.8 billion in lost productivity. 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 2017 Global Fact Sheet, 1 in 11 adults has diabetes (approximately 425 million people) and 12% of global health expenditure is spent on diabetes (approximately $727 billion).

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 Shock Wave 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 three studies performed at Montana State University that high-energy, acoustic pressure shock waves are disrupting biofilms and thus can be used for surface cleaning monuments, ship hulls, and underwater structure 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. Also, our technology should have a significant environmental impact by eliminating or reducing the use of harmful chemicals, which are the preferred biofilm cleaning method at this time.

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 from 2006 and our internal projections, the United States advanced wound healing market for the dermaPACE is estimated at $20 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 and cleared by the FDA on December 28, 2017.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions.

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

The key elements of our strategy include the following:

Commercialize and support the domestic distribution of our dermaPACE device to treat diabetic foot ulcers.

We initially focused 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. On December 28, 2017, the FDA notified the Company to permit the marketing of the dermaPACE System for the treatment of diabetic foot ulcers in the United States. We began the commercialization of dermaPACE in the United States in 2018 through strategic partnerships and will begin commercialization of the product ourselves in 2019. For example, in February 2018, we entered into an agreement with Premier Shockwave Wound Care, Inc. (“PSWC”) and Premier Shockwave, Inc. (“PS”) for the purchase by PSWC and PS of dermaPACE Systems and related equipment sold by us, including a minimum purchase of 100 units over 3 years, and granting PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain government healthcare facilities in exchange for the payment of certain royalties to us. PSWC is a related party since it is owned by A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company.

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 cardiac 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 will continue from sales of the devices and related applicators in these markets. We intend to continue to add additional distribution partners in the Americas, Middle East, Africa, 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 2018 and 2017 and recorded

stock-based compensation expense of $164,800 and $40,884 for the years ended December 31, 2018 and 2017, respectively.

Sales, Marketing and Distribution

Following FDA approval in December 2017, we intend to seek a development and/or commercialization partnership, or to 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. Three distributors and partners accounted for 33%, 23% and 11% of revenues for the year ended December 31, 2018, and 24%, 60% and 7% of accounts receivable at December 31, 2018. Three distributors accounted for 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017.

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 Suwanee, Georgia consists of 10,177 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-eight issued United States patents and eighteen issued foreign patents, which on average have remaining useful lives of ten years with the longest useful life extending to 2036. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations, piezoelectric fiber shock wave devices, chemical components for shock wave generation, reflector geometries, medical systems general construction, 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, blood sterilization, stem cell stimulation, tissue cleaning, 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 eleven United States non-provisional patent applications and seven foreign patent applications. Our patent-pending rights include inventions directed to certain shock wave 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, to destroy pathogens, to process fluids, meat and dairy products, to destroy blood vessels occlusions and plaques, and to perform personalized medical treatments. 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, 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. Refer to section "Contractual Obligations" for information on the default of our loan with HealthTronics.

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 European Community) 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), Orthotripsy® (United States). We are phasing out the Reflectron® (Germany and Switzerland) and Reflectrode® (Germany and Switzerland) trademarks due to the fact that these two products are no longer available for sale in any market.

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 also pursued the alleged 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. In 2016, SwiTalis claimed copyright rights on the High Voltage Modules that were used in our devices and the old line of Pulse Vet devices during the manufacturing process at Swisstronics in Switzerland. At this time, however, no such court action against Swisstronics is pending in Switzerland and we believe that it is unlikely that SwiTalis will pursue their earlier allegations against Swisstronics and, indirectly, us. In 2017, we abandoned our action against SwiTalis. There can be no assurance, however, that future claims or lawsuits against us may not be brought, and 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 Acelity (formerly Kinetic Concepts, Inc.), 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 Acelity) 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 shock wave 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 post market 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.

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 un-cleared 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;

the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experiences associated with use of the product; and

post market surveillance, including documentation of clinical experience and also follow-on, confirmatory studies.

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 shock waves (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 2018, we applied for two, new CPT Category III codes for extracorporeal shock wave therapy (ESWT) in wound healing. These codes were published by AMA/CPT for use beginning January 1, 2019.

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.

Confidentiality and Security of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), contains provisions that protect individually identifiable health information from unauthorized use or disclosure by covered entities and their business associates. The Office for Civil Rights of HHS, the agency responsible for enforcing HIPAA, has published regulations to address the privacy (the "Privacy Rule") and security (the "Security Rule") of protected health information ("PHI"). HIPAA also requires that all providers who transmit claims for health care goods or services electronically utilize standard transaction and data sets and to standardize national provider identification codes. In addition, the American Recovery and Reinvestment Act ("ARRA") enacted the HITECH Act, which extends the scope of HIPAA to permit enforcement against business associates for a violation, establishes new requirements to notify the Office for Civil Rights of HHS of a breach of HIPAA, and allows the Attorneys General of the states to bring actions to enforce violations of HIPAA. Rules implementing various aspects of HIPAA are continuing to be promulgated.

We anticipate that, as we expand our dermaPACE business, we will in the future be a covered entity under HIPAA. We intend to adopt policies and procedures to comply with the Privacy Rule, the Security Rule and the HIPAA statute as such regulations become applicable to our business and as such regulations are in effect at such time.

In addition to the HIPAA Privacy Rule and Security Rule described above, we may become subject to state laws regarding the handling and disclosure of patient records and patient health information. These laws vary widely. Penalties for violation include sanctions against a laboratory's licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against us for a violation of a state's privacy laws. We intend to adopt policies and procedures to ensure material compliance with state laws regarding the confidentiality of health information as such laws become applicable to us and to monitor and comply with new or changing state laws on an ongoing basis.

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.

Employees

As of March 28, 2019, we had a total of fourteen full time employees and two temporary employees in the United States. Of these, eight 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 for the commercialization of the dermaPACE and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $11,631,394 and $5,537,936 for the years ended December 31, 2018 and 2017, respectively. These operating losses and the events of default on the notes payable to HealthTronics, Inc., the Company's convertible promissory notes and

the Company's short term notes payable create uncertainty about our ability to continue as a going concern.

At December 31, 2018, we had cash and cash equivalents totaling $364,549 and negative working capital of $15,403,609. For the years ended December 31, 2018 and 2017, our net cash used by operating activities was $3,621,172 and $1,528,971, respectively. Management expects the cash used in operations for the Company will be approximately $225,000 to $300,000 per month for the first half of 2019 and $275,000 to $350,000 per month for the second half of 2019 as resources are devoted to the commercialization of the dermaPACE product including hiring of new employees, expansion of our international business and continued research and development of non-medical uses of our technology.

The continuation of our business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2019 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 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 required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. 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.

In addition, we may have potential liability for certain sales, offers or issuances of equity securities of the Company in possible violation of federal securities laws. Pursuant to a Registration Statement on Form S-1 (Registration No. 333-208676), declared effective on February 16, 2016 (the "2016 Registration Statement"), the Company sought to register: a primary offering of up to $4,000,000 units, the Common Stock included as part of the units, the warrants included as part of the units, and the Common Stock issuable upon exercise of such warrants; a primary offering of up to $400,000 placement agent warrants and the Common Stock issuable upon exercise of such placement agent warrants; and a secondary offering of 23,545,144 shares of Common Stock held by certain selling stockholders named in the 2016 Registration Statement. The SEC Staff's interpretations provides that, when an issuer is registering units composed of common stock, common stock purchase warrants, and the common stock underlying the warrants, the registration fee is based on the offer price of the units and the exercise price of the warrants. The registration fee paid did include the fee based on the offer price of the units, allocated to the unit line item in the fee table. Although the fee table in the 2016 Registration Statement included a line item for the Common Stock underlying the warrants, the Company did not include in that line item the fee payable based on the exercise price of $0.08 per share for such warrants, which amount should have been allocated to such line item based on the SEC Staff's interpretations. As a result, a portion of the securities intended to be registered by the 2016 Registration Statement was not registered. In addition, in a post-effective amendment to the 2016 Registration Statement filed on September 23, 2016, too many placement agent warrants were inadvertently deregistered. The post-effective amendment stated that the Company had issued $180,100, based on 2,251,250 Class L warrants issued with a $0.08 exercise price of warrants to the placement agent and therefore deregistered $219,900, based on 2,748,750 Class L warrants issued with a $0.08 exercise price of placement agent warrants from the $400,000, based on 5,000,000 Class L warrants issued with a $0.08 exercise price total offering amount included in the Registration Statement. The actual warrants issued to the placement agent totaled $240,133.36, based on 3,001,667 Class L warrants issued with a $0.08 exercise price, and only $159,867, based on 1,998,338 Class L warrants issued with a $0.08 exercise price should have been deregistered in such post-effective amendment. To the extent that we have not registered or failed to maintain an effective registration statement with respect to any of the transactions in securities described above and with respect to our ongoing offering of shares of Common Stock underlying the warrants, and a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible holders of our securities that participated in these offerings would have a right to rescind their transactions, and the Company may have to refund any amounts paid for the securities, which could have a materially adverse effect on the Company's financial condition. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act with respect to these transactions, but they could file a

claim in the future. Furthermore, the ongoing offering of and issuance of shares of Common Stock underlying certain of our warrants from the 2016 Registration Statement may have been, andmay continue to be, in violation of Section 5 of the Securities Act and the rules and regulations under the Securities Act, because we did not update the prospectus in the 2016 Registration Statement for a period of time after the 2016 Registration Statement was declared effective and because our reliance on Rule 457(p) under the Securities Act in an amendment to our Registration Statement on Form S-1 (Registration No. 333-213774) filed on September 23, 2016 effected a deregistration of the securities registered under the 2016 Registration Statement. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible securityholders would have a right to rescind their transactions, and the Company may have to refund any amounts paid the securities, which could have a materially adverse effect on the Company’s financial condition.

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, 2018, we had a net loss of $11,631,394 and used $3,621,172of cash in operations. For the year ended December 31, 2017, we had a net loss of $5,537,936 and used $1,528,971 of cash in operations. As of December 31, 2018, we had an accumulated deficit of $116,602,778 and a total stockholders' deficit of $15,356,099. 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 commercialization of the dermaPACE System and research and development of the non-medical uses of the PACE technology. Even if we succeed in developing and commercializing the dermaPACE System or any other 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. Additionally, we will be required to make mandatory prepayments of principal to HealthTronics, Inc. on the notes payable, related parties equal to 20% of the proceeds received through the issuance or sale of any equity securities in cash or through the licensing of our patents or other intellectual property rights.

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:

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;

the impact of changes in U.S. health care law and policy 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;

delays in timing of receipt of required regulatory approvals;

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.

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. Furthermore, our licensing and collaboration agreements are subject to counterparty risk, and to the extent the licensors or other third parties that we enter into licensing, joint venture or other collaboration arrangements with face operational, regulatory or financial difficulties, and to the extent we are unable to find suitable alternative counterparties in a timely manner, if at all, our business and results of operations could be materially adversely affected. 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.

Many of our product component materials are only produced by a single supplier for such product component. 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. Many of our product component materials are only produced by a single supplier for such product component, 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.

We currently sell our products through distributors and partners whose sales account for the majority of our revenues and accounts receivable. Our business and results of operations could be adversely affected by any business disruptions or credit or other financial difficulties experienced by such distributors or partners.

A majority of our revenues, and a majority of our accounts receivable, are from distributors and partners. Three distributors and partners accounted for 33%, 23% and 11% of revenues for the year ended December 31, 2018, and 24%, 60% and 7% of accounts receivable at December 31, 2018. Three distributors and partners accounted for 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017. To the extent that our distributors or partners experience any business disruptions or credit or other financial difficulties, our revenues and the collectability of our accounts receivable could be negatively impacted. If we are unable to establish, on a timely basis, relationships with new distributors or partners, our business and results of operations could be negatively impacted.

We have identified control deficiencies in our internal control over financial reporting that constitute a material weakness in our internal control over financial reporting. If we are unable to remediate these control deficiencies including this material weakness, we may not be able to accurately or timely report our financial condition or results of operations, which could cause investors to lose confidence in our reported financial information and thereby adversely affect the market price of our common stock.

As disclosed in Item 9A of this Annual Report on Form 10-K, management concluded that we had three material weaknesses in our internal control over financial reporting process. 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. The first material weakness is due to the lack of internal expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distribution agreements. The second material weakness is due to the lack of internal resources to analyze and properly apply generally accepted accounting principles to accounting for equity components of service agreements with select vendors. Management believes the material weaknesses identified above were due to the complex and non-routine nature of the Company’s complex financial instruments and derivatives, as well as lack of internal resources and expertise. The third material weakness relates to our information technology infrastructure. This material weakness is due to cybersecurity breaches from email spoofing, which occurred in 2019.

As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective as of December 31, 2018 and our disclosure controls and procedures were not effective as of December 31, 2018. Certain of these control deficiencies were also in existence as of December 31, 2017, but we are actively engaged in developing and implementing remedial measures designed to address these control deficiencies including the identified material weakness, but we have not remedied these matters as of the date of this Annual Report on Form 10-K and can provide no assurance that we will be successful in remediating these deficiencies or the material weakness in a timely manner, or at all, or that we will not identify additional deficiencies and material weaknesses in the future. If our remedial measures are insufficient to address these deficiencies or the material weakness, or if additional material weaknesses or deficiencies in our internal control over financial reporting are discovered or occur in the future, we may not be able to accurately or timely report our financial condition or results of operations, which could cause investors to lose confidence in our reported financial information and thereby adversely affect the perception of our business and the market price of our common stock. See “Item 9A—Controls and Procedures.”

We have entered into an agreement with companies owned by a current board member and stockholder that could delay or prevent an acquisition of our company and could result in the dilution of our shareholders in the event of our change of control.

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc. (“PSWC”) and Premier Shockwave, Inc. (“PS”), each of which is owned by A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. Among other terms, the agreement contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. Such provision may have the effect of delaying or deterring a change in control of us, and as a result could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. In addition, in the event we do experience a change of control, such provision may cause dilution of our existing shareholders in the event that PSWC exercises its option to require the Company to purchase all issued and

outstanding shares of PSWC and the Company finances some or all of such purchase price through equity issuances.

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

As a small company with sixteen employees, our success depends on the continuing contributions of our management team and qualified personnel. Turnover, transitions or other disruptions in our management team and personnel could make it more difficult to successfully operate our business and achieve our business goals and could adversely affect our results of operation and financial condition. 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.

We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.

We rely to a large extent upon sophisticated information technology systems to operate our businesses, some of which are managed, hosted, provided and/or used by third parties or their vendors. We collect, store and transmit large amounts of confidential information, and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact our operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers’ systems, portable media or storage devices. We could also experience, and in some cases have experienced in the past, a business interruption, theft of confidential information, financial theft, or reputational damage from industrial espionage attacks, malware, spoofing or other cyber-attacks, which may compromise our system infrastructure, lead to data leakage, either internally or at our third-party providers, or materially adversely impact our financial condition. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us.

We generate a portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

A portion of our revenue comes from international sources, and we anticipate that we will continue to expand our overseas operations. Engaging in international business involves a number of difficulties and risks, including:

required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste.

required compliance with anti-bribery laws, data privacy requirements, labor laws and anti-competition regulations.

export or import restrictions.

various reimbursement and insurance regimes.

laws and business practices favoring local companies.

political and economic instability.

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers.

foreign exchange controls. and

difficulties protecting or procuring intellectual property rights.

As we expand internationally, our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

Provisions in our Articles of Incorporation, Bylaws and Nevada law might decrease the chances of an acquisition.

Provisions of our Articles of Incorporation and Bylaws and applicable provisions of Nevada law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Some of the following provisions in our Articles of Incorporation and Bylaws that implement these are:

stockholders may not vote by written consent;

advance notice of business to be brought is required for a meeting of the Company’s stockholders;

no cumulative voting rights for the holders of common stock in the election of directors; and

vacancies in the board of directors may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

In addition, Section 78.438 of the Nevada Revised Statutes prohibits a publicly-held Nevada corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 10% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

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 identify 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.

Uncertainty surrounding and future changes to healthcare law in the United States may have a material adverse effect on us.

The healthcare regulatory environment in the United States is currently subject to significant uncertainty and the industry may in the future continue to experience fundamental change as a result of regulatory reform. In March 2010, the former U.S. President 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, and new legislation was passed in January 2018 such that the tax will be delayed until January 1, 2020;

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.

However, some of the provisions of the PPACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges. Furthermore, President Trump has vowed to repeal the PPACA, and it is uncertain whether new legislation will be enacted to replace the PPACA. On January 20, 2017, President Trump signed an executive order stating that the administration intended to seek prompt repeal of the healthcare reform law, and, pending repeal, directed the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the healthcare reform law. On October 12, 2017, President Trump signed another executive order directing certain federal

agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the healthcare reform law. The U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In the coming years, 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, False Claims Act 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.

Our operations may also implicate the False Claims Act. If we fail to comply with federal and state documentation, coding and billing rules, we could be subject to liability under the federal False Claims Act, including criminal and/or civil penalties, loss of licenses and exclusion from the Medicare and Medicaid programs. The False Claims Act prohibits individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government.

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, False Claims Act and similar state laws. We believe our operations are in compliance with the Federal Anti-Kickback Statute, False Claims Act 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, False Claims Act 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.

Failure to comply with the HIPAA Privacy, Security and Breach Notification Regulations, as such rules become applicable to our business, may increase our operational costs.

The HIPAA privacy and security regulations establish comprehensive federal standards with respect to the uses and disclosures of PHI by certain entities including health plans and health care providers, and set standards to protect the confidentiality, integrity and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including, for example: the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient. a patient's right to access, amend and receive an accounting of certain disclosures of PHI. the content of notices of privacy practices describing how PHI is used and disclosed and individuals' rights with respect to their PHI. and implementation of administrative, technical and physical safeguards to protect privacy and security of PHI. We anticipate that, as we expand our dermaPACE business, we will in the future be a covered entity under HIPAA. We intend to adopt policies and procedures to comply with the Privacy Rule, the Security Rule and the HIPAA statute as such regulations become applicable to our business and as such regulations are in effect at such time; however, there can be no assurance that our policies and procedures will be adequate or will prevent all incidents of non-compliance with such regulations.

The privacy regulations establish a uniform federal standard but do not supersede state laws that may be more stringent. Therefore, as we expand our deramPACE business, we may also be required to comply with both federal

privacy and security regulations and varying state privacy and security laws and regulations. The federal privacy regulations restrict the ability to use or disclose certain individually identifiable patient health information, without patient authorization, for purposes other than payment, treatment or health care operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations.

The HITECH Act and its implementing regulations also require healthcare providers to notify affected individuals, the Secretary of the U.S. Department of Health and Human Services, and in some cases, the media, when PHI has been breached as defined under and following the requirements of HIPAA. Many states have similar breach notification laws. In the event of a breach, to the extent such regulations are applicable to our business, we could incur operational and financial costs related to remediation as well as preparation and delivery of the notices, which costs could be substantial. Additionally, HIPAA, the HITECH Act, and their implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, private parties may also seek damages under state laws for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, amendments to HIPAA provide that the state Attorneys General may bring an action against a covered entity for a violation of HIPAA. As we expand our business such that federal and state laws regarding PHI and privacy apply to our operations, any noncompliance with such regulations could have a material adverse effect on our business, results of operations and financial condition.

We face periodic reviews and billing audits from governmental and private payors and these audits could have adverse results that may negatively impact our business.

As a result of our participation in the Medicare and Medicaid programs, we are subject to various governmental reviews and audits to verify our compliance with these programs and applicable laws and regulations. We also are subject to audits under various government programs in which third-party firms engaged by the Centers for Medicare & Medicaid Services conduct extensive reviews of claims data and medical and other records to identify potential improper payments under the Medicare program. Private pay sources also reserve the right to conduct audits. If billing errors are identified in the sample of reviewed claims, the billing error can be extrapolated to all claims filed which could result in a larger overpayment than originally identified in the sample of reviewed claims. Our costs to respond to and defend reviews and audits may be significant and could have a material adverse effect on our business, financial condition, results of operations and cash flows. Moreover, an adverse review or audit could result in:

required refunding or retroactive adjustment of amounts we have been paid by governmental or private payors.

state or Federal agencies imposing fines, penalties and other sanctions on us.

loss of our right to participate in the Medicare program, state programs, or one or more private payor networks. or

damage to our business and reputation in various markets.

Any one of these results could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 agencies 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 or may claim that the products of our suppliers, manufacturers or contract service providers that produce our devices infringe on their intellectual property. 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 market (OTCQB), which is an inter-dealer 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 OTCQB 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 293 shares of Series B Convertible Preferred Stock were converted to 3,657,278 shares of Common Stock on April 29, 2016. Although we have no shares of preferred stock currently outstanding and 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 Suwanee, Georgia, consisting of 10,177 square feet of space under a lease which expires on December 31, 2021. Under the terms of the lease, we pay monthly rent of $14,651, subject to a 3% adjustment on an annual basis.

Item 3. LEGAL PROCEEDINGS

We are engaged in various legal actions, claims and proceedings arising in the ordinary course of business, including claims related to breach of contracts and intellectual property matters resulting from our business activities. As with most actions such as these, an estimation of any possible and/or ultimate liability cannot always be determined.

There are no 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 MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

The Company's common stock is quoted on the OTCQB under the symbol "SNWV".

Holders of Common Stock

As of March 28, 2019, there were 149 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	31,703,385	$0.29	4,628,281
Total	31,703,385	$0.29	4,628,281

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 non-statutory 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 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 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

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding our business development plans, clinical trials, regulatory reviews, timing, strategies, expectations, anticipated expenses levels, projected profits, business prospects and positioning with respect to market, demographic and pricing trends, business outlook, technology spending and various other matters (including contingent liabilities and obligations and changes in accounting policies, standards and interpretations) and express our current intentions, beliefs, expectations, strategies or predictions. These forward-looking statements are based on a number of assumptions and currently available information and are subject to a number of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections titled “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors” and elsewhere in this Annual Report on Form 10-K. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K.

Overview

We are a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies and cleared by the U.S. Food and Drug Administration (FDA) on December 28, 2017.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. In 2018, we started marketing our dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

Our lead product candidate for the global wound care market, dermaPACE, has received FDA clearance for commercial use to treat diabetic foot ulcers in the United States and the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. We believe we have demonstrated that our patented technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe and Asia.

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

wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;

orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;

plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and

cardiac applications for removing plaque due to atherosclerosis improving heart muscle performance.

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

On December 28, 2017, the FDA notified the Company to permit the marketing of the dermaPACE system for the treatment of diabetic foot ulcers in the United States.

On September 27, 2017, we entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA (“MundiMed”), effective as of September 25, 2017, for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed will pay the Company an initial upfront distribution fee, with monthly upfront distribution fees payable thereafter over the following eighteen months. Profits from the joint venture are distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial upfront distribution fee was received on October 6, 2017. Monthly upfront distribution fee payments have been received through May 2018. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company received a response letter stating that the Company was in default of the agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. The Company is currently in discussions with a new partner to take over this agreement for the marketing and distribution of its products in Brazil.

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation (“PSWC”), and Premier Shockwave, Inc., a Georgia Corporation (“PS”). The agreement provides for the purchase by PSWC and PS of dermaPACE System and related equipment sold by the Company and includes a minimum purchase of 100 units over 3 years. The agreement grants PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. Under the agreement, the Company is responsible for the servicing and repairs of such dermaPACE Systems and equipment. The agreement also contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. The agreement also contains certain transfer restrictions on the stock of PSWC. Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company.

On June 26, 2018, the Company entered into an Agreement with Johnfk Medical Inc. (“FKS”), effective as of June 14, 2018, pursuant to which the Company and FKS committed to enter into a joint venture for the manufacture, sale and distribution of the Company’s dermaPACE and orthoPACE devices. Under the Agreement, FKS paid the Company a fee of $500,000 for initial distribution rights in Taiwan on June 22, 2018, with an additional fee of $500,000 for initial distribution rights in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam (the “SEA Region”) to be paid in the fourth quarter of 2018. On September 21, 2018, the Company entered into a joint venture agreement (the “JV Agreement”) with FKS setting forth the terms of the operation, management and control of a joint venture entity initially with the name of Holistic Health Institute Pte. Ltd., a private limited company to be incorporated in the Republic of Singapore, but with such company name subject to confirmation by Singapore Government. On November 9, 2018, the joint venture entity was incorporated in the Republic of Singapore with the

name of Holistic Wellness Alliance Pte. Ltd. (“HWA”). HWA was formed as a joint venture of the Company and FKS for the manufacture, sale and distribution of the Company’s dermaPACE® and orthoPACE® devices. Under the JV Agreement, the Company and FKS each hold shares constituting fifty percent of the issued share capital of HWA. The Company provides to HWA FDA and CE approved products for an agreed cost, access to treatment protocols, training, marketing and sales materials and management expertise, and FKS provides to HWA capital, human capital and sales resources in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam, certain reports and identification of new key opinion leaders as well as clinical trial and poster access availability. The JV Agreement also established the corporate governance of HWA, including a five-person board of directors consisting of two directors designated by the Company, two directors designated by FKS, and a third director appointed jointly by the parties. Initially, net profits under the JV Agreement shall be used to repay FKS for (i) the payment of $500,000 on June 22, 2018 to the Company for initial distribution rights in Taiwan and (ii) the cash advance to HWA per the terms of the JV Agreement. The JV Agreement includes other customary terms, including regarding the transfer of shares, indemnification and confidentiality.

The Company entered into short term notes payable with twenty-four individuals between June 26, 2018 and March 13, 2019 in the total principal amount of $2,835,525 with an interest rate of 5% per annum. The principal and accrued interest are due and payable six months from the date of issuance or receipt of notice of warrant exercise. On December 26, 2018, the Company defaulted on the short term notes payable issued on June 26, 2018 and began accruing interest at the default interest rate of 10%. On January 2, 2019, the Company defaulted on the short term notes payable issued on July 2, 2018 and began accruing interest at the default interest rate of 10%. On January 30, 2019, the Company defaulted on the short term notes payable issued on July 30, 2018 and began accruing interest at the default interest rate of 10%.

On October 10, 2018, the Company entered into short term notes payable with Shri P. Parikh, the President of the Company, in the total principal amount of $100,000 with an interest rate of 5% per annum. The principal and accrued interest are due and payable on the earlier of (i) one day after receipt of payment from Johnfk Medical Inc., (ii) six months from the date of issuance and (iii) the acceleration of the maturity of the short term note by the holder upon the occurrence of an event of default.

On October 17, 2018, the Company and a vendor agreed to settle a portion of a previously incurred fee for services in Common Stock in lieu of cash. On October 17, 2018, the Company issued 426,176 shares for services rendered May 2017 through February 2018.

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder.

Clinical Trials and Marketing

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.

The dermaPACE system was evaluated using two studies under IDE G070103. The studies were designed as prospective, randomized, double-blind, parallel-group, sham-controlled, multi-center 24-week studies at 39 centers. A total of 336 subjects were enrolled and treated with either dermaPACE plus conventional therapy or conventional therapy (a.k.a. standard of care) alone. Conventional therapy included, but was not limited to, debridement, saline-moistened gauze, and pressure reducing footwear. The objective of the studies was to compare the safety and efficacy of the dermaPACE device to sham-control application. The prospectively defined primary efficacy endpoint for the dermaPACE studies was the incidence of complete wound closure at 12 weeks post-initial application of the dermaPACE system (active or sham). Complete wound closure was defined as skin re-epithelialization without drainage or dressing requirements, confirmed over two consecutive visits within 12-weeks. If the wound was considered closed for the first time at the 12 week visit, then the next visit was used to confirm closure. Investigators continued to follow subjects and evaluate wound closure through 24 weeks.

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 patient enrollment for the second, supplemental clinical trial began in June 2013. We completed enrollment for the 130 patients in this second trial in November 2014 and suspended further enrollment at that time.

The only significant difference between the two studies was the number of applications of the dermaPACE device. Study one (DERM01; n=206) prescribed four (4) device applications/treatments over a two-week period, whereas,

study two (DERM02; n=130) prescribed up to eight (8) device applications (4 within the first two weeks of randomization, and 1 treatment every two weeks thereafter up to a total of 8 treatments over a 10-week period). If the wound was determined closed by the PI during the treatment regimen, any further planned applications were not performed.

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm2 and 16cm2, inclusive. Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 – Day 0), the first treatment was applied (either dermaPACE or Sham Control application). Applications with either dermaPACE or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

A total of 336 patients were enrolled in the dermaPACE studies at 37 sites. The patients in the studies were followed for a total of 24 weeks. The studies' primary endpoint, wound closure, was defined as "successful" if the skin was 100% re-epithelialized 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, 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=0.320). There were 39 out of 172 (22.67%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 30 out of 164 (18.29%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, and in conjunction with the FDA agreement to analyze the efficacy analysis carried over the full 24 weeks of the study, 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 61 (35.47%) dermaPACE subjects achieving complete wound closure compared with 40 (24.39%) of sham-control subjects (p=0.027). At the 24 week endpoint, the rate of wound closure in the dermaPACE® cohort was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023.

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 ($p<0.05$).

The proportion of patients with wound closure indicate a statistically significant difference between the dermaPACE and the control group in the proportion of subjects with the target-ulcer not closed over the course of the study (p-value=0.0346). Approximately 25% of dermaPACE® subjects reached wound closure per the study definition by day 84 (week 12). The same percentage in the control group (25%) did not reach wound closure until day 112 (week 16). These data indicate that in addition to the proportion of subjects reaching wound closure being higher in the dermaPACE® group, subjects are also reaching wound closure at a faster rate when dermaPACE is applied.

dermaPACE demonstrated superior results in the prevention of wound expansion (≥ 10% increase in wound size), when compared to the control, over the course of the study at 12 weeks (18.0% versus 31.1%; p=0.005, respectively).

At 12 and 24 weeks, the dermaPACE group had a higher percentage of subjects with a 50% wound reduction compared to the control (p=0.0554 and p=0.0899, respectively). Both time points demonstrate a trend towards statistical significance.

The mean wound reduction for dermaPACE subjects at 24 weeks was 2.10cm2 compared to 0.83cm2 in the control group. There was a statistically significant difference between the wound area reductions of the two cohorts from the 6 week follow-up visit through the end of the study.

Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 7.7% in the dermaPACE group compared with 11.6% 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 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.

Working with MCRA, we submitted to FDA a de novo petition on July 23, 2016. Due to the strong safety profile of our device and the efficacy of the data showing statistical significance for wound closure for dermaPACE subjects at 20 weeks, we believe that the dermaPACE device should be considered for classification into Class II as there is no legally marketed predicate device and there is not an existing Class III classification regulation or one or more approved PMAs (which would have required a reclassification under Section 513(e) or (f)(3) of the FD&C Act). On December 28, 2017, the FDA determined that the criteria at section 513(a)(1)(A) of (B) of the FD&C Act were met and granted the de novo clearance classifying dermaPACE as Class II and available to be marketed immediately.

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, New Zealand and South Korea.

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

Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. We expect to devote substantial resources for the commercialization of the dermaPACE System and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $11,631,394 and $5,537,936 for the years ended December 31, 2018 and 2017, respectively. These factors and the events of default on the notes payable to HealthTronics, Inc., the Company's convertible promissory notes and the Company's short term notes payable create substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the financial statement issuance date.

The continuation of our business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2019 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 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 required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. . 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, 2018, we had an accumulated deficit of $116,602,778. Although the size and timing of our future operating losses are subject to significant uncertainty, we anticipate that our operating losses will continue over the next few years as we incur expenses related to commercialization of our dermaPACE system for the treatment of diabetic foot ulcers in the United States. If we are able to successfully commercialize, market and distribute the dermaPACE system, then we hope to partially or completely offset these losses in the future. 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 and marketing 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 channels and partnerships, including our efforts to expand our marketing, sales and distribution reach through joint ventures and other contractual arrangements;

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 warrants and warrant liability, and the estimated fair value of stock-based compensation. 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, liabilities related to warrants issued, 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

Refer to Notes 6 and 17 to the accompanying consolidated financial statements.

Liabilities Related to Warrants Issued

We record certain common stock warrants we issued at fair value and recognize the change in the fair value of such warrants as a gain or loss, which we report in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. We report these warrants at fair value and classified as liabilities because they contain certain down-round provisions allowing for reduction of their exercise price. We estimate the fair value of these warrants using a binomial options pricing model.

Warrants Related to Debt Issued

We record a warrant discount related to warrants issued with debt at fair value and recognize the cost using the straight-line method over the term of the related debt as interest expense, which we report in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. We report this warrant discount as a reduction of the related debt liability.

Beneficial Conversion Feature on Convertible Debt

We record a beneficial conversion feature related convertible debt at fair value and recognize the cost using the straight-line method over the term of the related debt as interest expense, which we report in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. We report this beneficial conversion feature as a reduction of the related debt liability.

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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.

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.

Results of Operations for the Years ended December 31, 2018 and 2017

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2018 were $1,850,060, compared to $738,527 for the same period in 2017, an increase of $1,111,533, or 151%. Revenue resulted primarily from sales in Europe and Asia/Pacific of our orthoPACE devices and related applicators, sales in the United States and Asia/Pacific of our dermaPACE devices and related applicators and upfront distribution fee from our Southeast Asia distribution agreement with FKS. The increase in revenue for 2018 is primarily due to initial sales of dermaPACE devices in the United States, 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 applicators.

Cost of revenues for the year ended December 31, 2018 were $693,664, compared to $241,970 for the same period in 2017. Gross profit as a percentage of revenues was 63% for the year ended December 31, 2018, compared to 67% for the same period in 2017. The decrease in gross profit as a percentage of revenues in 2018 was primarily due to reduced margin on sales of devices to distribution partners and increase in new applicators which have a lower margin and higher shipping costs. This was partially offset by increased revenue for refurbishment license and upfront distribution fee which have little or no related cost, as compared to 2017.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2018 were $1,663,838, compared to $1,292,531 for the same period in 2017, an increase of $371,307, or 29%. The increase in research and development expenses in 2018, as compared to 2017, was due to an increase in salary and benefits of $263,628 as a result of hiring and contracting for temporary services and increased consulting expenses of $72,972 related to our insurance reimbursement strategy for the commercialization of dermaPACE.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2018 were $6,650,484, as compared to $3,004,403 for the same period in 2017, an increase of $3,646,081, or 121%. The increase in general and administrative expenses in 2018, as compared to 2017, was due to an increase in salary and benefits and recruitment fees related to new hires of $1,062,594, increased legal costs of $196,845 associated with SEC filings and patent issuance and maintenance, increased travel of $156,986 related to tradeshows and joint venture with FKS, and increased non-cash stock based compensation of $1,696,665 related to stock option and stock warrants issued in 2018 to new and existing employees.

Depreciation

Depreciation for the year ended December 31, 2018 was $22,332, compared to $24,069 for the same period in 2017, a decrease of $1,737, or 7%. The decrease was due to the lower depreciation related to devices as some devices were fully depreciated throughout the year.

Other Income (Expense)

Other income (expense) was a net expense of $4,451,136 for the year ended December 31, 2018 as compared to a net expense of $1,713,490 for the same period in 2017, an increase of $2,737,646, or 160%, in the net expense. The increase was primarily due to increased interest expense, beneficial conversion discount and debt discount related to the convertible promissory notes issued in the fourth quarter of 2017 and first quarter of 2018, as well as increased interest expense as a result of issuance of short term notes payable in the fourth quarter of 2018. In addition, the net expense in 2018 included a non-cash gain of $55,376 for a valuation adjustment on outstanding warrants, as compared to a non-cash loss of $568,729 for a valuation adjustment on outstanding warrants in 2017.

Net Loss

Net loss for the year ended December 31, 2018 was $11,631,394, or ($0.08) per basic and diluted share, compared to a net loss of $5,537,936, or ($0.04) per basic and diluted share, for the same period in 2017, an increase in the net loss of $6,093,458, or 110%. The increase in the net loss was primarily a result of increase in operating expenses and interest expense as explained above.

Liquidity and Capital Resources

We expect to devote substantial resources for the commercialization of the dermaPACE System and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $11,631,394 and $5,537,936 for the years ended December 31, 2018 and 2017, respectively. These factors and the events of default on the notes payable to HealthTronics, Inc., the Company’s convertible promissory notes and the Company’s short term notes payable create substantial doubt about the Company’s ability to continue as a going concern for a period of at least twelve months from the financial issuance date.

The continuation of our business is dependent upon raising additional capital to fund operations. Management expects the cash used in operations for the Company will be approximately $225,000 to $300,000 per month for the first half of 2019 and $275,000 to $350,000 per month for the second half of 2019 as resources are devoted to the commercialization of the dermaPACE product including hiring of new employees, expansion of our international business and continued research and development of non-medical uses of our technology. Management’s plans are to obtain additional capital in 2019 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, 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 required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. 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.

In addition, we may have potential liability for certain sales, offers or issuances of equity securities of the Company in possible violation of federal securities laws. Pursuant to a Registration Statement on Form S-1 (Registration No. 333-208676), declared effective on February 16, 2016 (the "2016 Registration Statement"), the Company sought to register: a primary offering of up to $4,000,000 units, the Common Stock included as part of the units, the warrants included as part of the units, and the Common Stock issuable upon exercise of such warrants; a primary offering of up to $400,000 placement agent warrants and the Common Stock issuable upon exercise of such placement agent warrants; and a secondary offering of 23,545,144 shares of Common Stock held by certain selling stockholders named in the 2016 Registration Statement. The SEC Staff's interpretations provide that, when an issuer is registering units composed of common stock, common stock purchase warrants, and the common stock underlying the warrants, the registration fee is based on the offer price of the units and the exercise price of the warrants. The registration fee paid did include the fee based on the offer price of the units, allocated to the unit line item in the fee table. Although the fee table in the 2016 Registration Statement included a line item for the Common Stock underlying the warrants, the Company did not include in that line item the fee payable based on the exercise price of $0.08 per share for such warrants, which amount should have been allocated to such line item based on the SEC Staff's interpretations. As a result, a portion of the securities intended to be registered by the 2016 Registration Statement was not registered. In addition, in a post-effective amendment to the 2016 Registration Statement filed on September 23, 2016, too many placement agent warrants were inadvertently deregistered. The post-effective amendment stated that the Company had issued $180,100, based on 2,251,250 Class L warrants issued with a $0.08 exercise price of warrants to the placement agent and therefore deregistered $219,900, based on 2,748,750 Class L warrants issued with a $0.08 exercise price of placement agent warrants from the $400,000, based on 5,000,000 Class L warrants issued with a $0.08 exercise price total offering amount included in the Registration Statement. The actual warrants issued to the placement agent totaled $240,133.36, based on 3,001,667 Class L warrants issued with a $0.08 exercise price, and only $159,867, based on 1,998,338 Class L warrants issued with a $0.08 exercise price should have been deregistered in such post-effective amendment. To the extent that we have not registered or failed to maintain an effective registration statement with respect to any of the transactions in securities described above and with respect to our ongoing offering of shares of Common Stock underlying the warrants, and a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible holders of our securities that participated in these offerings would have a right to rescind their transactions, and the Company may have to refund any amounts paid for the securities, which could have a materially adverse effect on the Company's financial condition. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act with respect to these transactions, but they could file a claim in the future. Furthermore, the ongoing offering of and issuance of shares of Common Stock underlying certain of our warrants from the 2016 Registration Statement may have been, and may continue to be, in violation of Section 5 of the Securities Act and the rules and regulations under the Securities Act, because we did not update the prospectus in the 2016 Registration Statement for a period of time after the 2016 Registration Statement was declared effective and because our reliance on Rule 457(p) under the Securities Act in an amendment to our Registration Statement on Form S-1 (Registration No. 333-213774) filed on September 23, 2016 effected a deregistration of the securities registered under the 2016 Registration Statement. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible securityholders would have a right to rescind their transactions, and the Company may have to refund any amounts paid the securities, which could have a materially adverse effect on the Company's financial condition.

On December 29, 2017, the Company entered into a line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. On June 21, 2018, the Company made a payment of $144,500 on the line of credit. On June 26, 2018, the amount of the line of credit was increased by $280,500. The line of credit may be called for payment upon demand.

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder. On October 5, 2018 and October 23, 2018, the Company received $15,000 and $40,000, respectively, as an increase in the line of credit.

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. (“NFS”) to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE System in the marketplace. This agreement provides for a lease line of up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company's accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company. As of February 27, 2018, we were in default of Master Equipment Lease due to the sale of equipment purchased under the Master Lease Agreement to a third party and, as a result, the note is callable by NFS or NFS. could have notified the Company to assemble all equipment for pick up. The Master Equipment Lease was paid in full on June 27, 2018.

On June 26, 2018, the Company entered into an agreement with Johnfk Medical Inc. (“FKS”), effective as of June 14, 2018, pursuant to which the Company and FKS committed to enter into a joint venture for the manufacture, sale and distribution of the Company’s dermaPACE and orthoPACE devices. On September 21, 2018, the Company entered into a joint venture agreement with FKS setting forth the terms of the operation, management and control of a joint venture entity initially with the name of Holistic Health Institute Pte. Ltd., a private limited company to be incorporated in the Republic of Singapore, but with such company name subject to confirmation by Singapore Government. On November 9, 2018, the joint venture entity was incorporated in the Republic of Singapore with the name of Holistic Wellness Alliance Pte. Ltd. Under the terms of the June 2018 agreement, FKS paid the Company a fee of $500,000 on June 22, 2018 for initial distribution rights in Taiwan. An additional fee of $500,000 for initial distribution rights in the SEA Region will be received in installments. The first two installments of $50,000 have been received and the remaining $400,000 is expected to be received in April 2019.

The Company entered into short term notes payable with twenty-four individuals between June 26, 2018 and March 13, 2019 in the total principal amount of $2,835,525 with an interest rate of 5% per annum. The principal and accrued interest are due and payable six months from the date of issuance or receipt of notice of warrant exercise. On December 26, 2018, the Company defaulted on the short term notes payable issued on June 26, 2018 and began accruing interest at the default interest rate of 10%. On January 2, 2019, the Company defaulted on the short term notes payable issued on July 2, 2018 and began accruing interest at the default interest rate of 10%. On January 30, 2019, the Company defaulted on the short term notes payable issued on July 30, 2018 and began accruing interest at the default interest rate of 10%.

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 we may be required to use some or all of the net proceeds to repay our indebtedness, 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, 2018 and 2017, net cash used by operating activities was $3,621,172 and $1,528,971, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The increase in the use of cash for operating activities for the year ended December 31, 2018, as compared to the same period for 2017, of $2,092,201, or 137%, was primarily due to the increase in accounts payable, accrued employee compensation and accrued expenses of $803,561 and increase in interest payable, related parties of $485,875. Net cash used by investing activities in 2018 was $42,888 as compared to net cash used by investing activities in 2017 of $0. The increase in cash used by investing activities is due to the purchase of property and equipment. Net cash provided by financing activities for the year ended December 31, 2018 was $3,317,510, which primarily consisted of the proceeds from short term notes of $1,637,497, net proceeds from convertible promissory notes of $1,159,785, proceeds from related party line of credit of $480,000, proceeds from advances from related parties of $144,000 and proceeds from warrant exercises of $40,728 which was offset by payment on related party line of credit of $144,500. Net cash provided by financing activities for the year ended December 31, 2017 was $2,117,298, which primarily consisted of the net proceeds from convertible promissory notes of $1,384,232, proceeds from related party line of credit of $370,000, proceeds from advances from related parties of $310,000 and proceeds from warrant exercises of $93,066. Cash and cash equivalents decreased by $365,635 for the year ended December 31, 2018 and cash and cash equivalents increased by $596,613 for the year ended December 31, 2017.

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 August 2016, we entered into a lease agreement for 7,500 square feet of office space for office, research and development, quality control, production and warehouse space which expires on December 31, 2021. On February 1, 2018, we entered into an amendment to the lease agreement for an additional 380 square feet of office space for storage which expires on December 31, 2021. On January 2, 2019, we entered into a second amendment to the lease agreement for an additional 2,297 square feet of office space for office space which expires on December 31, 2021. Under the terms of the lease, we pay monthly rent of $14,651, subject to a 3% adjustment on an annual basis.

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, 2018 and 2017.

On August 3, 2017, the Company and HealthTronics, Inc. entered into a third amendment (the “Third Amendment”) to amend certain provisions of the notes payable, related parties. The Third Amendment provides for the extension of the due date to December 31, 2018, revision of the mandatory prepayment provisions and the future issuance of additional warrants to HealthTronics upon certain conditions.

Since December 31, 2018, the Company has been in default under the notes, as amended by the Third Amendment, and as a result HealthTronics, Inc. could, among other rights and remedies, exercise its rights under the security agreement granting HealthTronics, Inc. a first priority security interest in the assets of the Company. The Company is in negotiations with HealthTronics, Inc. to address the event of default.

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. See Note 2 to the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

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

Effects of Inflation

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

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2018 and 2017

	2018	2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$364,549	$730,184
Accounts receivable, net of allowance for doubtful accounts of $33,045 in 2018 and $92,797 in 2017	234,774	152,520
Due from related party	1,228	-
Inventory	357,820	231,532
Prepaid expenses and other current assets	125,111	90,288
TOTAL CURRENT ASSETS	1,083,482	1,204,524
PROPERTY AND EQUIPMENT, net	77,755	60,369
OTHER ASSETS	16,491	13,917
TOTAL ASSETS	$1,177,728	$1,278,810
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$1,592,643	$1,496,523
Accrued expenses	689,280	673,600
Accrued employee compensation	340,413	1,680
Contract liabilities	131,797	-
Advances payable	-	310,000
Line of credit, related parties	883,224	370,179
Accrued interest, related parties	1,171,782	685,907
Short term notes payable	1,883,163	-
Convertible promissory notes, net	2,652,377	455,606
Notes payable, related parties, net	5,372,743	5,222,259
Warrant liability	1,769,669	1,943,883
TOTAL CURRENT LIABILITIES	16,487,091	11,159,637
NON-CURRENT LIABILITIES		
Contract liabilities	46,736	-
TOTAL NON-CURRENT LIABILITIES	46,736	-
TOTAL LIABILITIES	16,533,827	11,159,637
COMMITMENTS AND CONTINGENCIES		

STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 designated; 0 shares issued and 0 shares outstanding in 2018 and 2017	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 designated; 0 shares issued and 0 shares outstanding in 2018 and 2017	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 155,665,138 and 139,300,122 issued and outstanding in 2018 and 2017, respectively	155,665	139,300
ADDITIONAL PAID-IN CAPITAL	101,153,882	94,995,040
ACCUMULATED DEFICIT	(116,602,778)	(104,971,384)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(62,868)	(43,783)
TOTAL STOCKHOLDERS' DEFICIT	(15,356,099)	(9,880,827)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,177,728	$1,278,810

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, 2018 and 2017

	2018	2017
REVENUES		
Product	$949,601	$456,765
License fees	819,696	235,878
Other revenue	80,763	45,884
TOTAL REVENUES	1,850,060	738,527
COST OF REVENUES		
Product	525,216	129,512
Other	168,448	112,458
TOTAL COST OF REVENUES	693,664	241,970
GROSS MARGIN	1,156,396	496,557
OPERATING EXPENSES		
Research and development	1,663,838	1,292,531
General and administrative	6,650,484	3,004,403
Depreciation	22,332	24,069
TOTAL OPERATING EXPENSES	8,336,654	4,321,003
OPERATING LOSS	(7,180,258)	(3,824,446)
OTHER INCOME (EXPENSE)		
Gain (loss) on warrant valuation adjustment	55,376	(568,729)
Interest expense	(4,496,148)	(1,139,711)
Other income, net	9,952	-
Loss on foreign currency exchange	(20,316)	(5,050)
TOTAL OTHER INCOME (EXPENSE), NET	(4,451,136)	(1,713,490)
NET LOSS	(11,631,394)	(5,537,936)
OTHER COMPREHENSIVE INCOME (LOSS)		
Foreign currency translation adjustments	(19,085)	8,286
TOTAL COMPREHENSIVE LOSS	$(11,650,479)	$(5,529,650)
LOSS PER SHARE:		
Net loss - basic and diluted	$(0.08)	$(0.04)

Weighted average shares outstanding - basic and diluted	149,537,777	138,838,602

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Years Ended December 31, 2018 and 2017

	Preferred Stock		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 Loss	Total
Balances as of December 31, 2016	-	$-	137,219,968	$137,220	$92,436,697	$(99,433,448)	$(52,069)	$(6,911,600)
Net loss	-	-	-	-	-	(5,537,936)	-	(5,537,936)
Warrant exercise	-	-	1,163,333	1,163	91,903	-	-	93,066
Cashless warrant exercise	-	-	866,625	867	66,100	-	-	66,967
Shares issued for services	-	-	50,196	50	7,950	-	-	8,000
Warrants issued for services	-	-	-	-	182,856	-	-	182,856
Stock-based compensation - options and warrants	-	-	-	-	768,105	-	-	768,105
Warrants issued with convertible promissory note	-	-	-	-	620,748	-	-	620,748
Beneficial conversion	-	-	-	-	820,681	-	-	820,681

feature on debt								
Foreign currency translation adjustment	-	-	-	-	-	-	8,286	8,286
Balances as of December 31, 2017	-	-	139,300,122	139,300	94,995,040	(104,971,384)	(43,783)	(9,880,827)
Net loss	-	-	-	-	-	(11,631,394)	-	(11,631,394)
Cashless warrant exercises	-	-	6,395,499	6,396	(6,396)	-	-	-
Proceeds from warrant exercise	-	-	422,939	423	40,305	-	-	40,728
Shares issued for services	-	-	1,049,340	1,049	180,451	-	-	181,500
Conversion of promissory notes	-	-	8,497,238	8,497	926,199	-	-	934,696
Warrants issued for services	-	-	-	-	828,690	-	-	828,690
Stock-based compensation - options	-	-	-	-	2,480,970	-	-	2,480,970
Warrants issued with convertible promissory notes	-	-	-	-	808,458	-	-	808,458
Beneficial conversion feature on convertible promissory notes	-	-	-	-	709,827	-	-	709,827
Warrants issued with promissory note	-	-	-	-	36,104	-	-	36,104
Beneficial conversion feature on promissory notes	-	-	-	-	35,396	-	-	35,396
Reclassification of warrant liability to equity	-	-	-	-	118,838	-	-	118,838

Foreign currency translation adjustment	-	-	-	-	-	-	(19,085)	(19,085)
Balances as of December 31, 2018	-	$-	155,665,138	$155,665	$101,153,882	$(116,602,778)	$(62,868)	$(15,356,099)

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, 2018 and 2017

	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(11,631,394)	$(5,537,936)
Adjustments to reconcile loss from operations to net cash used by operating activities		
Depreciation	22,332	24,069
Bad debt expense (recovery)	(59,752)	57,601
Stock-based compensation	2,480,970	768,105
Loss (gain) on warrant valuation adjustment	(55,376)	568,729
Amortization of debt issuance costs	2,767,361	431,087
Amortization of debt discount	150,484	110,247
Stock issued for consulting services	181,500	8,000
Warrants issued for consulting services	828,690	182,856
Accrued interest	410,289	21,896
Interest payable, related parties	485,875	576,481
Changes in assets and liabilities		
Accounts receivable - trade	(22,502)	250,678
Inventory	(123,118)	(7,079)
Prepaid expenses	(34,823)	(2,465)
Other	(3,802)	(131)
Accounts payable	276,120	783,559
Accrued expenses	188,708	298,512
Accrued employee compensation	338,733	(63,180)
Contract liabilties	178,533	-
NET CASH USED BY OPERATING ACTIVITIES	(3,621,172)	(1,528,971)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(42,888)	-
NET CASH USED BY INVESTING ACTIVITIES	(42,888)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from short term note	1,637,497	-
Proceeds from convertible promissory notes, net	1,159,785	1,384,232
Proceeds from line of credit, related party	624,000	370,000
Advances from related parties	-	310,000
Proceeds from note payable, product	96,708	-
Proceeds from warrant exercise	40,728	93,066
Payment on line of credit, related party	(144,500)	-

Payments on note payable, product	(96,708)	-
Payments on short term loan	-	(40,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,317,510	2,117,298
EFFECT OF EXCHANGE RATES ON CASH	(19,085)	8,286
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(365,635)	596,613
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	730,184	133,571
CASH AND CASH EQUIVALENTS, END OF PERIOD	$364,549	$730,184
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$151,227	$-
NONCASH INVESTING AND FINANCING ACTIVITIES		
Reclassification of warrant liability to equity	$118,838	$-
Advances payable converted to convertible promissory notes	$310,000	$-
Accounts payable converted to convertible promissory notes	$120,000	$-
Beneficial conversion feature on convertible debt	$745,223	$820,681
Warrants issued with debt	$844,562	$620,748
Conversion of 10% convertible promissory notes	$934,696	$-

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

1. Description of the Business and Going Concern and Management's Plans

SANUWAVE Health, Inc. and Subsidiaries (the "Company") is a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. The Company's initial focus is regenerative medicine – utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. The Company's lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. On December 28, 2017, the U.S. Food and Drug Administration (the "FDA") notified the Company to permit the marketing of the dermaPACE System for the treatment of diabetic foot ulcers in the United States. In 2018, the Company started marketing its dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia, and Asia/Pacific. The Company generates revenue streams from product sales, licensing transactions and other activities.

As shown in the accompanying consolidated financial statements, the Company incurred a net loss of $11,631,394 and $5,537,936 during the years ended December 31, 2018 and 2017, respectively, and the net cash used by operating activities was $3,621,172 and $1,528,971, respectively. As of December 31, 2018, the Company had a net working capital deficit of $15,403,609, total stockholders' deficit of $15,356,099 and cash and cash equivalents of $364,549. These factors and the events of default on the notes payable to HealthTronics, Inc. (see Note 12), the Company's convertible promissory notes (see Note 10) and the Company's short term notes payable (see Note 9) raise substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the financial statement issuance date.

The Company does not currently generate significant recurring revenue and will require additional capital during 2019. Although no assurances can be given, management of the Company believes that existing capital resources should enable the Company to fund operations into the second quarter of 2019.

The continuation of the Company's business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2019 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 required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

2. Summary of significant accounting policies

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. 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 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 ("U.S. GAAP"). 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, estimate of the net realizable value of inventory, estimated reserves for inventory, valuation of derivatives, the determination of the valuation allowances for deferred taxes, estimated fair value of stock-based compensation, and estimated fair value of warrants.

Reclassifications – Certain accounts in the prior period consolidated financial statements have been reclassified for comparison purposes to conform to the presentation of the current period consolidated financial statements. These reclassifications had no effect on the previously reported net loss.

Cash and cash equivalents - For purposes of the consolidated financial statements, liquid instruments with an original maturity of 90 days or less when purchased are considered 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. Three distributors and partners accounted for 33%, 23% and 11% of revenues for the year ended December 31, 2018, and 24%, 60% and 7% of accounts receivable at December 31, 2018. Three distributors accounted for 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017.

The Company depends on suppliers for product component materials and other components that are subject to stringent regulatory requirements. The Company currently purchases most of its 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, 2018 and 2017

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, which is valued using the first in, first out ("FIFO") method, or net 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.

Depreciation of property and equipment - The straight-line method of depreciation is used for computing depreciation on property and equipment. The costs of additions and betterments are capitalized and expenditures for repairs and maintenance, which do not extend the economic useful life of the related assets, are expensed. Depreciation is based on estimated useful lives as follows: machines and equipment, 3 years; devices, 5 - 15 years; office and computer equipment, 3 years; furniture and fixtures, 3 years; and software, 2 years.

Fair value of financial instruments - The carrying values of accounts payable 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.

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 Company recognizes 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. (See Note 15).

The Company's notes payable approximate fair value because the terms are substantially similar to comparable debt in the marketplace.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

2. Summary of significant accounting policies (continued)

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.

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. Fees from services performed are recognized when the service is performed. License fee for refurbishment of applicators will be recognized at the time the customer is granted the license to refurbish the applicators. Revenue will be calculated using the transaction price that represents the most likely consideration to be received for the license times the number of licenses issued. Fees for upfront distribution license agreements will be recognized on a straight-line basis over the term of the contract. See Note 17 for further discussion.

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

Income taxes - Income taxes are accounted for utilizing the asset and liability method. 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. Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements as of December 31, 2018 and 2017. The Company does not expect any significant changes in the unrecognized tax benefits within twelve months of the reporting date.

The Company will recognize in income tax expense, interest and penalties related to income tax matters. For the years ended December 31, 2018 and 2017, the Company did not have any amounts recorded for interest and penalties.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

2. Summary of significant accounting policies (continued)

Loss per share - 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, 2018 and 2017, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. Anti-dilutive equity securities consists of the following at December 31, 2018 and 2017, respectively:

	2018	2017
Stock options	31,703,385	21,593,385
Warrants	103,994,927	97,977,851
Convertible promissory notes	24,112,518	14,641,190
Anti-dilutive equity securities	159,810,830	134,212,426

Comprehensive income –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 for its employee stock option program. Stock-based compensation expense for all stock-based payment awards is based on the estimated fair value of the award. For employees and directors, the award is measured on the grant date. For non-employees, the award is measured on the grant date and is then remeasured at each vesting date and financial reporting date. The Company recognizes the estimated fair value of the award as compensation cost over the requisite service period of the award, which is generally the option vesting term. The Company generally issues new shares of common stock to satisfy option and warrant exercises.

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, consulting fees for FDA submissions, universities performing non-medical related research and insurance premiums for clinical studies and non-medical research. 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.

Liabilities related to warrants issued – The Company records certain common stock warrants issued at fair value and recognizes the change in the fair value of such warrants as a gain or loss, which is reported in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. The Company reports these warrants at fair value and classified as liabilities because they contain certain down-round provisions allowing for reduction of their

exercise price. The fair value of these warrants is estimated using a binomial options pricing model.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

2. Summary of significant accounting policies (continued)

Warrants related to debt issued – The Company records a warrant discount related to warrants issued with debt at fair value and recognizes the cost using the straight-line method over the term of the related debt as interest expense, which is reported in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. This warrant discount is reported as a reduction of the related debt liability.

Beneficial conversion feature on convertible debt -The Company records a beneficial conversion feature related convertible debt at fair value and recognizes the cost using the straight-line method over the term of the related debt as interest expense, which is reported in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. This beneficial conversion feature is reported as a reduction of the related debt liability.

Recently issued or adopted accounting standards

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASC 606), which supersedes nearly all existing revenue recognition guidance under U. S. GAAP. The core principle of ASC 606 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. ASC 606 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 can be adopted using either of the following transition methods: (i) a full retrospective method, which requires the standard to be applied to each prior period presented, or (ii) a modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to the opening retained earnings in the period of adoption. The Company adopted ASC 606 on a modified retrospective basis as of January 1, 2018. The Company completed an assessment of customer contracts and concluded that the adoption of ASC 606 did not have a material impact on its consolidated financial statements; therefore, no cumulative-effect adjustment was recorded on the adoption date. The disclosures related to revenue recognition have been significantly expanded under the standard, specifically around the quantitative and qualitative information about performance obligations and disaggregation of revenue. The expanded disclosure requirements are included in Notes 6 and 17.

In February 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 “Codification Improvements to Topic 842, Leases” and ASU No. 2018-11 “Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company expects to adopt ASU 2016-02 effective January 1, 2019. Upon

adoption of Topic 842, the Company expects recognition of additional assets and corresponding liabilities pertaining to its operating leases on its consolidated balance sheets. The Company is evaluating the requirements of this guidance and has not yet determined the impact on its consolidated balance sheet and statements of operations.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

2. Summary of significant accounting policies (continued)

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments (Topic 230). This ASU will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The ASU will be effective for fiscal years beginning after December 15, 2017. This standard requires adoption on a retrospective basis unless it is impracticable to apply, in which case it would be required to apply the amendments prospectively as of the earliest date practicable. The new standard was adopted during the first quarter of 2018 using a retrospective transition method. The adoption of this guidance did not have a material impact on our financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies what constitutes a modification of a share-based payment award. The ASU is intended to provide clarity and reduce both diversity in practice and cost and complexity when applying the guidance in Topic 718 to a change to the terms or conditions of a share-based payment award. ASU 2017-09 is effective for public entities January 1, 2018. The Company does not anticipate that the adoption of ASU 2017-09 will have a material impact on its financial condition or results of operations.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480): Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this ASU addresses the complexity and reporting burden associated with the accounting for freestanding and embedded instruments with down round features as liabilities subject to fair value measurement. Part II of this ASU addresses the difficulty of navigating Topic 480. Part I of this ASU will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for an entity in an interim or annual period. The Company anticipates applying Part I of this ASU at the effective date of January 1, 2019 and is in the process of evaluating the impact of the pending adoption on the Company’s financial position.

In June 2018, the FASB issued ASU 2018-07, Compensation – Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting. This ASU simplifies the accounting for share- based payments to nonemployees by aligning it with the accounting for share-based payments to employees. As a result, share-based payments issued to nonemployees related to the acquisition of goods and services will be accounted for similarly to the accounting for share-based payments to employees, with certain exceptions. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within such fiscal years. Early adoption is permitted if financial statements have not yet been issued. The Company is currently evaluating the impact of the adoption of ASU 2018-07 on the Company’s financial position.

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements (“ASU 2018-09”). These amendments provide clarifications and corrections to certain ASC subtopics including the following: Income Statement - Reporting Comprehensive Income – Overall (Topic 220-10), Debt - Modifications and Extinguishments (Topic 470-50), Distinguishing Liabilities from Equity – Overall (Topic 480-10), Compensation - Stock Compensation - Income Taxes (Topic 718-740), Business Combinations - Income Taxes (Topic 805-740), Derivatives and Hedging – Overall (Topic 815- 10), and Fair Value Measurement – Overall (Topic 820-10). The majority of the amendments in ASU 2018-09 will be effective in annual periods beginning after December 15, 2018. The Company is currently evaluating and assessing the impact this guidance will have on its financial position or results of operations.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

2. Summary of significant accounting policies (continued)

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”). The amendments in ASU 2018-13 modify the disclosure requirements associated with fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2018-13 and its impact on its consolidated financial statements.

3.
Inventory

Inventory consists of the following at December 31, 2018 and 2017:

	2018	2017
Inventory - finished goods	$250,821	$136,534
Inventory - parts	226,299	167,613
Gross inventory	477,120	304,147
Provision for losses and obsolescence	(119,300)	(72,615)
Net inventory	$357,820	$231,532

4.
Property and equipment

Property and equipment consists of the following at December 31, 2018 and 2017:

	2018	2017
Machines and equipment	$240,295	$240,295
Office and computer equipment	196,150	156,860
Devices	81,059	89,704

Software	38,126	34,528
Furniture and fixtures	16,019	16,019
Other assets	2,259	2,259
Total	573,908	539,665
Accumulated depreciation	(496,153)	(479,296)
Net property and equipment	$77,755	$60,369

Depreciation expense was $22,332 and $24,069 for the years ended December 31, 2018 and 2017, respectively. The depreciation policies followed by the Company are described in Note 2.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

5.
Accrued expenses

Accrued expenses consist of the following at December 31, 2018 and 2017:

	2018	2017
Accrued board of director's fees	$200,000	$125,000
Accrued executive severance	136,000	118,000
Accrued outside services	115,118	165,427
Accrued related party advance	101,137	-
Accrued travel	58,993	39,926
Deferred rent	44,623	51,191
Accrued clinical study expenses	13,650	13,650
Accrued computer equipment	8,752	-
Accrued audit and tax preparation	-	73,800
Accrued legal and professional fees	-	61,890
Deferred revenue	-	13,317
Accrued other	11,007	11,399
	$689,280	$673,600

The Company is a party to a Severance and Advisory Agreement (the “Severance Agreement”) with its former President and Chief Executive Officer, and a director of the Company. Pursuant to the Severance Agreement, the former executive 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 in 2014. The accrued executive severance at December 31, 2018 and 2017 represents the unpaid portion of the bonus payments plus accrued interest due to late payment.

On October 10, 2018, the Company entered into accrued related party advance with Shri P. Parikh, the President of the Company, in the total principal amount of $100,000 with an interest rate of 5% per annum. The principal and accrued interest are due and payable on the earlier of (i) one day after receipt of payment from Johnfk Medical Inc., (ii) six months from the date of issuance and (iii) the acceleration of the maturity of the short term note by the holder upon the occurrence of an event of default.

On May 1, 2017, the Company entered into an agreement with a firm to provide business advisory and consulting services. The compensation for those services was to be paid in a combination of cash and common stock. At December 31, 2017, the Company accrued $120,000 of expense for the services provided. In March 2018, the Company issued 467,423 shares of common stock for services provided in 2017 and 66,026 shares of common stock for services provided in 2018.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2018 and 2017

6.
Contract liabilities

As of December 31, 2018, the Company has contract assets and liabilities from contracts with customers (see Note 17).

Contract liabilities consist of the following:

	December 31, 2018	December 31, 2017
Deposit on product	$92,950	$-
Service agreement	57,365	-
Other	28,218	-
Total Contract liabilities	178,533	-
Non-Current	(46,736)	-
Total Current	$131,797	$-

The timing of the Company's revenue recognition may differ from the timing of payment by its customers. A contract asset (receivable) is recorded when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the satisfaction of performance obligations, the Company records a contract liability (deferred revenue) until the performance obligations are satisfied. Of the aggregate $178,533 of contract liability balances as of December 31, 2018, the Company expects to satisfy its remaining performance obligations associated with $131,797 and $46,736 of contract liability balances within the next twelve months and following twelve months, respectively. Deferred revenue as of December 31, 2017 was de minimus to the consolidated financial statements.

7.
Advances payable

The Company has received cash advances to help fund the Company's operations. On January 10, 2018, the outstanding balance of the $310,000 of advances payable was converted into two 10% Convertible Promissory Notes (see Note 10). On November 12, 2018, the advances payable balance was added to the outstanding balance line of credit, related parties.

As of December 31, 2017, A. Michael Stolarski and Kevin A. Richardson II, both members of the Company's board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The convertible promissory notes for this balance were issued on January 10, 2018 (see Note 10).

8.
Line of credit, related parties

The Company entered into a line of credit agreement with a member of the board of directors and an existing shareholder at December 29, 2017. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. On November 12, 2018, the Company entered into an amendment to the line of credit agreement. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder. The line of credit, related parties had an aggregate outstanding balance of $883,224 and $370,179 as of December 31, 2018 and 2017, respectively.

Interest expense on line of credit, related parties totaled $33,724 and $179 for the years ended December 31, 2018 and 2017, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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9.
Short term notes payable

The Company entered into short term notes payable between June 26, 2018 and December 31, 2018 in the total principal amount of $1,870,525 with an interest rate of 5% per annum. The principal and accrued interest of $1,883,163 as of December 31, 2018 are due and payable six months from the date of issuance of the respective notes , of which $233,028 are held by an officer and director of the Company.

On December 26, 2018, the Company defaulted on the short term notes payable issued on June 26, 2018 and began accruing interest at the default interest rate of 10%. On January 2, 2019, the Company defaulted on the short term notes payable issued on July 2, 2018 and began accruing interest at the default interest rate of 10%. On January 30, 2019, the Company defaulted on the short term notes payable issued on July 30, 2018 and began accruing interest at the default interest rate of 10%.

10.
Convertible promissory notes

In 2017, the Company began offering subscriptions for 10% convertible promissory notes (the “10% Convertible Promissory Notes”) to selected investors. The 10% Convertible Promissory Notes have a six month term from the subscription date and the note holders can convert the 10% Convertible Promissory Notes at any time during the term to the number of shares of Company common stock, $0.001 par value (the “Common Stock”), equal to the amount obtained by dividing (i) the amount of the unpaid principal and interest on the note by (ii) $0.11. During the year ended December 31, 2018, the Company issued $1,596,000 in the aggregate principal amount of 10% Convertible Promissory Notes, including $430,000 purchased by officers and directors. During the year ended December 31, 2017, the Company issued $1,533,750 in the aggregate principal amount of 10% Convertible Promissory Notes.

The 10% Convertible Promissory Notes include a warrant agreement (the “Class N Warrant”) to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount by (ii) $0.11. The Class N Warrants expire March 17, 2019. On January 23, 2019, the Company extended the expiration date to May 1, 2019 and on March 1, 2019, the Company extended the expiration date to June 28, 2019. During the years ended December 31, 2018 and 2017, the Company issued 14,509,090 and 13,943,180, respectively, Class N Warrants in connection with the closings of 10% Convertible Promissory Notes.

Pursuant to the terms of a Registration Rights Agreement (the “Registration Rights Agreement”) that the Company entered with the investors in connection with the 10% Convertible Promissory Notes, the Company is required to file a registration statement that covers the shares of Common Stock issuable upon conversion of the 10% Convertible Promissory Notes or upon exercise of the Class N 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. As of the date of the filing of this report the registration statement has not yet been filed. At this time, the monetary penalty has been determined by management to be de minimis.

The Company recorded $709,827 debt discount for the beneficial conversion feature of the promissory notes, $808,458 in debt discount for the discount on the Class N Warrant agreement and $77,715 in debt issuance costs to be amortized over the lives of the 10% Convertible Promissory Notes during 2018. The Company recorded $820,681 debt discount for the beneficial conversion feature of the promissory notes, $620,748 in debt discount for the discount

on the Class N Warrant agreement and $89,518 in debt issuance costs to be amortized over the lives of the 10% Convertible Promissory Notes during 2017. The Company recorded $508,866 in debt issuance costs for Class N Warrants issued per the engagement letter with West Park Capital.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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10.
Convertible promissory notes (continued)

The calculated fair value of the Class N Warrants was determined using the Black-Scholes pricing model based on the following assumptions:

	December 31, 2018	December 31, 2017
Weighted average contractual term in years	1.13 - 1.19	1.25 - 1.39
Weighted average risk free interest rate	1.98% - 2.15%	1.63% - 1.89%
Weighted average volatility	94.43% - 98.63%	86.62% - 103.21%
Forfeiture rate	0.0%	0.0%
Expected dividend yield	0.0%	0.0%

Additional debt issuance costs will be incurred and amortized over the remaining lives of the 10% Convertible Promissory Notes when Class N Warrants are issued per the engagement letter with West Park Capital. On June 29, 2018, the Company issued 1,242,955 Class N Warrants to West Park Capital per the terms of a placement agent agreement and $417,633 was expensed as interest expense. On October 4, 2018, the Company issued 1,242,954 Class N Warrants to West Park Capital per the terms of a placement agent agreement and $91,233 was expensed as interest expense.

On February 15, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on August 15, 2017 and began accruing interest at the default interest rate of 18%. On May 3, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on November 3, 2017 and began accruing interest at the default interest rate of 18%. On May 30, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on November 30, 2017 and began accruing interest at the default interest rate of 18%. On June 22, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on December 22, 2017 and began accruing interest at the default interest rate of 18%. On July 10, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on January 10, 2018 and began accruing interest at the default interest rate of 18%. On August 2, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on February 2, 2018 and began accruing interest at the default interest rate of 18%.

The 10% Convertible Promissory Notes had an aggregate outstanding principal balance of $2,652,377, net of $0 beneficial conversion feature, warrant discount and debt issuance costs and $455,606, net of $1,099,861 beneficial conversion feature, warrant discount and debt issuance costs at December 31, 2018 and 2017, respectively.

Interest expense on the 10% Convertible Promissory Notes totaled $3,565,198 and $452,804 for the years ended December 31, 2018 and 2017, respectively.

Kevin A. Richardson II, CEO, chairperson of the Company’s board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $260,000 and was issued 2,363,636 Class N Warrants for the year ended December 31, 2018. A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $170,000 and $330,000 and was issued 1,545,455 and 3,000,000 Class N Warrants for the years ended December 31, 2018 and 2017, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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10.
Convertible promissory notes (continued)

On January 29, 2018, the Company entered into an additional 10% Convertible Promissory Note with an accredited investor in the amount of $71,500 and issued 650,000 Class N Warrants in connection with such 10% Convertible Promissory Note. The Company intends to use the proceeds from such 10% Convertible Promissory Note for payment of services to an investor relations company and the account of the attorney updating the Registration Statement on Form S-1 of the Company filed under the Securities Act of 1933, as amended, on January 3, 2017 (File No. 333-213774), which registration statement shall also register the shares issuable upon conversion of such 10% Convertible Promissory Note and issuable upon the exercise of a Class N Warrants issued concurrently with the issuance of such 10% Convertible Promissory Note.

The Company recorded $35,396 debt discount for the beneficial conversion feature of the 10% Convertible Promissory Note and $36,104 in debt discount for the discount on the Class N Warrant agreement to be amortized over the life of the 10% Convertible Promissory Note.

The 10% Convertible Promissory Note was converted in full in August 2018 (See Note 14).

11.
Notes payable, product, related party

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE System in the marketplace. This agreement provides for a lease line of credit up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company's accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company. NFS Leasing Inc. was a purchaser of the 10% Convertible Promissory Notes (see Note 10) and thus, is considered a related party.

On March 1, 2018, the Company entered into the first drawdown of the Master Equipment Lease in the amount of $96,708.

Interest expense on note payable, product totaled $20,909 for the year ended December 31, 2018.

As of February 27, 2018, we were in default of Master Equipment Lease due to the sale of equipment purchased under the Master Lease Agreement to a third party and, as a result, the note was callable by NFS Leasing, Inc. or NFS Leasing, Inc. could have notified the Company to assemble all equipment for pick up. The notes payable, product was paid in full on June 27, 2018.

12.
Notes payable, related parties

The notes payable, related parties as amended were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. The notes payable, related parties bear interest at 8% per annum, as amended. All remaining unpaid accrued interest and principal is due on December 31, 2018, as amended. HealthTronics, Inc. is a related party because they are a shareholder in the Company and have a security agreement

with the Company detailed below.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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12.
Notes payable, related parties (continued)

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. Events of Default under the notes payable, related parties have occurred and are continuing on account of the failure of SANUWAVE, Inc., a Delaware corporation, a wholly owned subsidiary of the Company and the borrower under the notes payable, related parties, to make the required payments of interest which were due on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017, December 31, 2017, June 30, 2018, September 30, 2018 and December 31, 2018 (collectively, the "Defaults"). As a result of the Defaults, the notes payable, related parties have been accruing interest at the rate of 10% per annum since January 2, 2017 and continue to accrue interest at such rate. 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 $5,372,743, net of $0 debt discount and $5,222,259, net of $150,484 debt discount at December 31, 2018, and 2017, respectively.

Accrued interest currently payable totaled $1,171,782 and $685,907 at December 31, 2018 and 2017, respectively. Interest expense on notes payable, related parties totaled $787,586 and $634,169 for the years ended December 31, 2018 and 2017, respectively.

As of January 1, 2017, we are in default with our interest payment and the note is callable by HealthTronics, Inc. The notes payable, related parties are shown as a current liability.

As of December 31, 2018, we are in default under the notes, as amended by the Third Amendment, and as a result HealthTronics, Inc. could, among other rights and remedies, exercise its rights under its first priority security interest in our assets. We are in negotiations with HealthTronics, Inc. to address the event of default.

13.
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 January 12, 2016, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series B 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 293 shares of preferred stock, par value $0.001 per share, as Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock has a stated value of $1,000 per share.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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13.
Preferred Stock (continued)

Under the Certificate of Designation, holders of Series B 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 B 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 B 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 B Convertible Preferred Stock eligible for conversion without exceeding the Beneficial Ownership Limitation.

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.

Thre are no shares of Series A or Series B Convertible Preferred Stock issued or outstanding as of December 31, 2018 and 2017.

14.
Equity Transactions

Conversion of 10% Convertible Promissory Notes

For the year ended December 31, 2018, the Company issued 8,497,238 shares of Common Stock upon the conversion of 10% Convertible Promissory Notes in the amount of $902,500 plus accrued interest of $32,197 at the conversion price of $0.11 per share per the terms of the 10% Convertible Promissory Notes agreement.

Warrant Exercise

For the year ended December 31, 2018, the Company issued 422,939 shares of common stock upon the exercise of 422,939 Class N Warrants, Series A Warrants and Class O Warrants to purchase shares of stock under the terms of the respective warrant agreements.

For the year ended December 31, 2017, the Company issued 1,163,333 shares of common stock upon the exercise of 1,163,333 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L Warrant agreement.

Cashless Warrant Exercise

For the year ended December 31, 2018, the Company issued 6,395,499 shares of common stock upon the exercise of 7,878,925 Class N Warrants, Series A Warrants and Class O Warrants to purchase shares of stock under the terms of the respective warrant agreements.

For the year ended December 31, 2017, the Company issued 866,625 shares of common stock upon the cashless exercise of 1,428,745 Class L Warrants and Series A Warrants to purchase shares of stock based on the current market value per share as of the date of conversion as determined under the terms of the respective warrant agreements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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14.
Equity Transactions (continued)

Consulting Agreement

In November 2017, the Company entered into a three month consulting agreement for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 26,667 and 23,529 shares, respectively in each of the first two months of the agreement. The $4,000 was recorded as a non-cash general and administrative expense during the year ended December 31, 2017.

In April 2018, the Company verbally entered into a month-to-month consulting agreement with a consultant for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 74,714 shares of Common Stock for services performed from January through June 2018. $20,000 was recorded as a non-cash general and administrative expense during the year ended December 31, 2018.

In May 2017, the Company entered into an agreement with an investment company to provide business advisory and consulting services. The compensation for those services was to be paid in a combination of cash and Common Stock. At December 31, 2017, the Company accrued $120,000 of expense for the services provided. The Common Stock was issued in March and June 2018 in the amount of 533,450 and 15,000 shares, respectively. On October 17, 2018, this agreement was verbally amended to provide for the cash compensation of services performed to be paid with Common Stock. The Common Stock was issued in October 2018 in the amount of 426,176 shares. The $37,500 was recorded as a non-cash general and administrative expense during the year ended December 31, 2018.

15.
Warrants

A summary of warrants as of December 31, 2018 and 2017, and the changes during the years ended December 31, 2018 and 2017, is presented as follows:

Warrant class	Outstanding as of December 31, 2016	Issued	Exercised	Outstanding as of December 31, 2017	Issued	Exercised	Expired	Outstanding as of December 31, 2018

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 K Warrants	5,200,000	2,000,000	-	7,200,000	-	-	-	7,200,000
Class L Warrants	65,945,005	-	(2,046,832)	63,898,173	-	(6,639,834)	-	57,258,339
Class N Warrants	-	13,943,180	-	13,943,180	17,644,999	(1,136,364)	-	30,451,815
Class O Warrants	-	6,540,000	-	6,540,000	1,509,091	(120,000)	-	7,929,091
Series A Warrants	2,106,594	-	(545,246)	1,561,348	-	(405,666)	-	1,155,682
	78,086,749	22,483,180	(2,592,078)	97,977,851	19,154,090	(8,301,864)	(4,835,150)	103,994,927

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15.
Warrants (continued)

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

	Exercise price/share	Expiration date
Class K Warrants	$0.08	June 2025
Class K Warrants	$0.11	August 2027
Class L Warrants	$0.08	May 2019
Class N Warrants	$0.11	June 2019
Class O Warrants	$0.11	June 2019
Series A Warrants	$0.03	May 2019

On January 23, 2019, the Company extended the expiration date to May 1, 2019 for Series A Warrants, Class L Warrants and Class N Warrants. On March 1, 2019, the Company extended the expiration date to June 28, 2019 for Class N Warrants and Class O Warrants.

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

On January 26, 2018, the Company issued Class O Warrant Agreements to a related party vendor to purchase 909,091 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $160,455 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019. On March 1, 2019, the Company extended the expiration date to June 28, 2019.

In 2018, the Company issued Class O Warrant Agreements to a vendor to purchase 600,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at their respective grant dates was $159,370 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019. On March 1, 2019, the Company extended the expiration date to June 28, 2019.

In August 2017, the Company, in connection with the Third Amendment (Note 10), issued to HealthTronics, Inc., an additional 2,000,000 Class K Warrants to purchase shares of the Company's Common Stock at an exercise price of $0.11 per share, subject to certain anti-dilution protection. The warrants vested upon issuance and expire after ten years.

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15.
Warrants (continued)

On November 30, 2017, the Company issued Class O Warrant Agreements to a vendor to purchase 2,500,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $174,731 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019.

On December 6, 2017, the Company issued Class O Warrant Agreements to a vendor to purchase 100,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $8,125 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019.

On December 11, 2017, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $285,810 and was recorded as research and development expense in the amount of $98,655 and general and administrative expense in the amount of $187,155 and an increase to additional paid-in capital for the full amount of $285,810. The warrants vested upon issuance and expire on March 17, 2019. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company's board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company's board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants as well as other employees of the Company.

The Class K Warrants and the Series A Warrants are derivative financial instruments. 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. 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 have been classified as Level 3 instruments and 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 which ranged from 0.21 to 8.6 years, the volatility of the Company's common stock price which ranged from 112% to 134%, and the risk-free interest rate which ranged from 2.43% to 2.64% for the year ended December 31, 2018. The remaining life of the warrants which ranged from 1.21 to 9.6 years, the volatility of the Company's common stock price which ranged from 109% to 133%, and the risk-free interest rate which ranged from 1.79% to 2.39% for the year ended December 31, 2017. In addition, as of the valuation dates, management

assessed the probabilities of future financing and other re-pricing events in the binominal valuation models.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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15.
Warrants (continued)

A summary of the changes in the warrant liability during the years ended December 31, 2018 and 2017, is as follows:

	Class K Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2016	$884,000	$358,120	$1,242,120
Issued	200,000	-	200,000
Redeemed	-	(66,966)	(66,966)
Change in fair value	532,000	36,729	568,729
Warrant liability as of December 31, 2017	1,616,000	327,883	1,943,883
Issued	-	-	-
Redeemed	-	(118,838)	(118,838)
Change in fair value	(74,000)	18,624	(55,376)
Warrant liability as of December 31, 2018	$1,542,000	$227,669	$1,769,669

16.
Commitments and contingencies

Operating Leases

The Company leases office and storage space. Rent expense for the years ended December 31, 2018 and 2017, was $157,395 and $159,583, respectively. Minimum future lease payments under the operating lease consist of the following:

Year ending December 31,	Amount
2019	$186,132
2020	191,712
2021	197,464
Total	$575,308

The Company has recorded a liability for deferred rent and is expensing rent on a straight line basis over the life of the lease.

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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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16.
Commitments and contingencies (continued)

Potential Liability Related to Issuances of Equity Securities

The Company may have potential liability for certain sales, offers or issuances of equity securities of the Company in possible violation of federal securities laws. Pursuant to a Registration Statement on Form S-1 (Registration No. 333-208676), declared effective on February 16, 2016 (the "2016 Registration Statement"), the Company sought to register: a primary offering of up to $4,000,000 units, the Common Stock included as part of the units, the warrants included as part of the units, and the Common Stock issuable upon exercise of such warrants; a primary offering of up to $400,000 placement agent warrants and the Common Stock issuable upon exercise of such placement agent warrants; and a secondary offering of 23,545,144 shares of Common Stock held by certain selling stockholders named in the 2016 Registration Statement. The SEC Staff's interpretations provide that, when an issuer is registering units composed of common stock, common stock purchase warrants, and the common stock underlying the warrants, the registration fee is based on the offer price of the units and the exercise price of the warrants. The registration fee paid did include the fee based on the offer price of the units, allocated to the unit line item in the fee table. Although the fee table in the 2016 Registration Statement included a line item for the Common Stock underlying the warrants, the Company did not include in that line item the fee payable based on the exercise price of $0.08 per share for such warrants, which amount should have been allocated to such line item based on the SEC Staff's interpretations. As a result, a portion of the securities intended to be registered by the 2016 Registration Statement was not registered. In addition, in a post-effective amendment to the 2016 Registration Statement filed on September 23, 2016, too many placement agent warrants were inadvertently deregistered. The post-effective amendment stated that the Company had issued $180,100, based on 2,251,250 Class L warrants issued with a $0.08 exercise price of warrants to the placement agent and therefore deregistered $219,900, based on 2,748,750 Class L warrants issued with a $0.08 exercise price of placement agent warrants from the $400,000, based on 5,000,000 Class L warrants issued with a $0.08 exercise price total offering amount included in the Registration Statement. The actual warrants issued to the placement agent totaled $240,133.36, based on 3,001,667 Class L warrants issued with a $0.08 exercise price, and only $159,867, based on 1,998,338 Class L warrants issued with a $0.08 exercise price should have been deregistered in such post-effective amendment. To the extent that the Company has not registered or failed to maintain an effective registration statement with respect to any of the transactions in securities described above and with respect to the ongoing offering of shares of Common Stock underlying the warrants, and a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible holders of securities that participated in these offerings would have a right to rescind their transactions, and the Company may have to refund any amounts paid for the securities, which could have a materially adverse effect on the Company's financial condition. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act with respect to these transactions, but they could file a claim in the future. Furthermore, the ongoing offering of and issuance of shares of Common Stock underlying certain of the warrants from the 2016 Registration Statement may have been, and may continue to be, in violation of Section 5 of the Securities Act and the rules and regulations under the Securities Act, because the Company did not update the prospectus in the 2016 Registration Statement for a period of time after the 2016 Registration Statement was declared effective and because the Company's reliance on Rule 457(p) under the Securities Act in an amendment to the Registration Statement on Form S-1 (Registration No. 333-213774) filed on September 23, 2016 effected a deregistration of the securities registered under the 2016 Registration Statement. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible securityholders would have a right to rescind their transactions, and the Company may have to refund any amounts

paid the securities, which could have a materially adverse effect on the Company's financial condition.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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Years Ended December 31, 2018 and 2017

17.
Revenue

The Company began accounting for revenue in accordance with ASC 606, which we adopted beginning January 1, 2018, using the modified retrospective method (see Note 2). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

Pursuant to ASC 606, we apply the following the five-step model:

1.
Identify the contract(s) with a customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

2.
Identify the performance obligation(s) in the contract. If a contract promises to transfer more than one good or service to a customer, each good or service constitutes a separate performance obligation if the good or service is distinct or capable of being distinct.

3.
Determine the transaction price. The transaction price is the amount of consideration to which the entity expects to be entitled in exchanging the promised goods or services to the customer.

4.
Allocate the transaction price to the performance obligations in the contract. For a contract that has more than one performance obligation, an entity should allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which an entity expects to be entitled in exchange for satisfying each performance obligation.

5.
Recognize revenue when (or as) the Company satisfies a performance obligation. For each performance obligation, an entity should determine whether the entity satisfies the performance obligation at a point in time or over time. Appropriate methods of measuring progress include output methods and input methods.

The Company recognizes revenue primarily from the following types of contracts:

Product sales

Product sales include devices and applicators (new and refurbished). Product sales revenue is recognized at the point in time where the customer obtains control of the goods and the Company satisfies its performance obligation, which is generally at the time the Company ships the product to the customer.

Licensing transactions

Licensing transaction include distribution licenses and intellectual property licenses. The Company's licenses are primarily symbolic licenses, with no significant stand-alone functionality. Symbolic licensing fee revenue is recognized over the time period that the Company satisfies its performance obligations, which is generally the term of the licensing agreement.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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17.
Revenue (continued)

Other activities

Other activities primarily include extended warranties, repairs and billed freight. Device product sales are bundled with an initial one-year warranty and the Company offers a separately priced second-year warranty. The Company allocates the device sales price to the product and the embedded warranty by reference to the stand-alone extended warranty price. Because the extended warranty represents a stand-ready obligation, revenue is recognized over the time period that the Company satisfies its performance obligations, which is generally the warranty term. Repairs (parts and labor) and billed freight revenue are recognized at the point in time that the service is performed, or the product is shipped, respectively.

Disaggregation of Revenue

The disaggregation of revenue is based on geographical region. The following table presents revenue from contracts with customers for the years ended December 31, 2018 and 2017:

	Year ended December 31, 2018			Year ended December 31, 2017		
	United States	International	Total	United States	International	Total
Product	$209,842	$739,759	$949,601	$-	$456,765	$456,765
License fees	25,000	794,696	819,696	25,000	210,878	235,878
Other Revenue	-	80,763	80,763	-	45,884	45,884
	$234,842	$1,615,218	$1,850,060	$25,000	$713,527	$738,527

18.
Related party transactions

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation (“PSWC”), and Premier Shockwave, Inc., a Georgia Corporation (“PS”). The agreement provides for the purchase by PSWC and PS of dermaPACE System and related equipment sold by the Company and includes a minimum purchase of 100 units over 3 years. The agreement grants PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. No royalties were earned during the year ended December 31, 2018. Under the agreement, the Company is responsible for the servicing and repairs of such dermaPACE Systems and equipment. The agreement also contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and

whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. The agreement also contains certain transfer restrictions on the stock of PSWC. Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company.

During the year ended December 31, 2018, the Company recorded $207,457 in product revenue from this related party. The Contract liabilities balance includes a balance of $156,565 from this related party.

On December 29, 2017, the Company entered into a line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand. The outstanding balance as of December 31, 2017 with accrued interest was $370,179 and $0 interest was paid for the period ending December 31, 2017.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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18.
Related party transactions (continued)

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder.

On December 11, 2017, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000 shares of common stock at an exercise price of $0.11 per share. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company's board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company's board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants.

On March 27, 2017, the Company began offering subscriptions for 10% convertible promissory notes (the "10% Convertible Promissory Notes") to selected accredited investors. The 10% Convertible Promissor Notes include a warrant agreement (the "Class N Warrant Agreement") to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount, by (ii) $0.11. The Class N Warrant Agreement expires March 17, 2019. On January 23, 2019, the Company amended the expiration date of the Class N Warrants from March 17, 2019 to May 1, 2019, effective as of January 23, 2019. A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $330,000. A. Michael Stolarski and Kevin A. Richardson II, both members of the Company's board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The 10% Convertible Promissory Notes associated with these subscriptions were issued in January 2018.

19.
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. As of December 31, 2018 and 2017, the Stock Incentive Plan reserved a total of 35,000,000 and 22,500,000, respectively, shares of common stock for grant. On December 31, 2018, there were 4,628,281 shares of common stock available for grant under the Stock Incentive Plan.

During the year ended December 31, 2018, the Company granted to employees, members of the board of directors and members of the Company's Medical Advisory Board options to purchase an aggregate of 10,110,000 shares of common stock under a previously issued incentive plan. The options have an exercise price between $0.11 and $0.42 per share for an aggregate grant date value of approximately $2,500,000. The options vested upon issuance and have a term of ten years.

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19.
Stock-based compensation (continued)

On June 15, 2017, the Company granted to the active employees, members of the board of directors and three members of the Company's Medical Advisory Board options to purchase an aggregate total of 5,550,000 shares of the Company's 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 $0.0869 per option resulting in compensation expense of $482,295. Compensation cost was recognized upon grant.

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, 2018 and 2017:

	2018	2017
Weighted average expected life in years	5.00	5.0
Weighted average risk free interest rate	2.84% - 3.21%	1.76%
Weighted average volatility	134% - 144.15%	120.00%
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. The expected volatility is based on the average volatility of the Company and that of peer group 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, 2018 and 2017, the Company recognized $2,480,970 and $482,295, respectively, as compensation cost related to options granted. As of December 31, 2018, and 2017, there are no unamortized compensation costs related to options granted.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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19.
Stock-based compensation (continued)

A summary of option activity as of December 31, 2018 and 2017, and the changes during the years then ended, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding at December 31, 2016	16,203,385	$0.38
Granted	5,550,000	$0.11
Exercised	-	$-
Forfeited or expired	(160,000)	$0.22
Outstanding at December 31, 2017	21,593,385	$0.31
Granted	10,110,000	$0.25
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at December 31, 2018	31,703,385	$0.29
Vested and exercisable at December 31, 2018	31,703,385	$0.29

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at December 31, 2018 and 2017, respectively. The aggregate intrinsic value for outstanding options was $2,085,866 and $2,073,641 at December 31, 2018 and 2017, respectively. The aggregate intrinsic value for all vested and exercisable options was $2,085,866 and $2,073,641 at December 31, 2018 and 2017, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options is 7.4 years and 7.37 years as of December 31, 2018 and 2017, respectively.

A summary of the Company’s nonvested options as of December 31, 2018 and 2017, and changes during the years then ended, is presented as follows:

Weighted

	Options	Average Exercise Price per share
Outstanding at December 31, 2016	-	$-
Granted	5,550,000	$0.11
Vested	(5,550,000)	$0.11
Forfeited or expired	-	$-
Outstanding at December 31, 2017	-	$-
Granted	10,110,000	$0.25
Vested	(10,110,000)	$0.25
Forfeited or expired	-	$-
Outstanding at December 31, 2018	-	$-

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20.
Joint ventures

On June 26, 2018, the Company entered into an Agreement with Johnfk Medical Inc. ("FKS"), effective as of June 14, 2018, pursuant to which the Company and FKS committed to enter into a joint venture for the manufacture, sale and distribution of the Company's dermaPACE and orthoPACE devices. Under the Agreement, FKS paid the Company a fee of $500,000 for initial distribution rights in Taiwan on June 22, 2018, with an additional fee of $500,000 for initial distribution rights in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam (the "SEA Region") to be paid in the first quarter of 2019. On September 21, 2018, the Company entered into a joint venture agreement (the "JV Agreement") with FKS setting forth the terms of the operation, management and control of a joint venture entity initially with the name of Holistic Health Institute Pte. Ltd., a private limited company to be incorporated in the Republic of Singapore, but with such company name subject to confirmation by Singapore Government. On November 9, 2018, the joint venture entity was incorporated in the Republic of Singapore with the name of Holistic Wellness Alliance Pte. Ltd. ("HWA"). HWA was formed as a joint venture of the Company and FKS for the manufacture, sale and distribution of the Company's dermaPACE and orthoPACE devices. Under the JV Agreement, the Company and FKS each hold shares constituting fifty percent of the issued share capital of HWA. The Company provides to HWA FDA and CE approved products for an agreed cost, access to treatment protocols, training, marketing and sales materials and management expertise, and FKS provides to HWA capital, human capital and sales resources in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam, certain reports and identification of new key opinion leaders as well as clinical trial and poster access availability. The V Agreement also established the corporate governance of HWA, including a five-person board of directors consisting of two directors designated by the Company, two directors designated by FKS, and a third director appointed jointly by the parties. Initially, net profits under the JV Agreement shall be used to repay FKS for (i) the payment of $500,000 on June 22, 2018 to the Company for initial distribution rights in Taiwan and (ii) the cash advance to HWA per the terms of the JV Agreement. The JV Agreement includes other customary terms, including regarding the transfer of shares, indemnification and confidentiality.

On September 27, 2017, the Company entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed was to pay the Company an initial upfront distribution fee, with monthly upfront distribution fees payable thereafter over the following eighteen months. Profits from the joint venture were to be distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial upfront distribution fee was received on October 6, 2017. Monthly upfront distribution fee payments have been received aggregating $372,222. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company received a response letter stating that the Company was in default of the agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. Accordingly, the Company derecognized the contract assets and contract liabilities associated with the MundiMed contract.

21.
Income taxes

The Company files income tax returns in the United States federal jurisdiction and various state and foreign jurisdictions. The Company is subject to United States federal and state income tax examinations by tax authorities for any years that have net operating losses open until the net operating losses are used.

The components of net loss before provision for income taxes for the years ended December 31, 2018 and 2017 are as follows:

	2018	2017
Domestic	$(12,031,115)	$(5,857,851)
Foreign	399,721	319,915
	$(11,631,394)	$(5,537,936)

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21.
Income taxes (continued)

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, 2018 and 2017:

	2018	2017
Current:		
Federal	$-	$-
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	(2,157,035)	8,371,516
State	(383,705)	1,489,172
Foreign	2,673	(19,224)
Change in valuation allowance	2,538,067	(9,841,464)
	$-	$-

On December 22, 2017, H.R. 1, commonly known as the Tax Cuts and Jobs Act (the “Act”) was signed into law. The Act reduced the Company’s corporate federal tax rate from 35% to 21% effective January 1, 2018 and changed certain other provisions. As a result, the Company is required to re-measure the deferred tax assets and liabilities using the enacted rate at which they expect them to be recovered or settled. The effect of this re-measurement is recorded to income tax expense in the year the tax law is enacted. For 2017, the re-measurement of our net deferred tax asset resulted in a $11.1 million adjustment to the income tax provision (benefit) at December 31, 2017. The transition tax is based on total post-1986 earnings and profits which were previously deferred from U.S. income taxes. At December 31, 2018 and 2017, the Company did not have any undistributed earnings of our foreign subsidiaries. As a result, no additional income or withholding taxes have been provided for. The Company does not anticipate any impacts of the global intangible low taxed income (“GILTI”) and base erosion anti-abuse tax (“BEAT”) and as such, the Company has not recorded any impact associated with either GILTI or BEAT.

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21.
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 21% for the years ended December 31, 2018 and 2017 to pretax loss from operations as a result of the following for the years ended December 31, 2018 and 2017:

	2018	2017
Tax benefit at statutory rate	$(2,442,593)	$(1,938,278)
Increase (reduction) in income taxes resulting from:		
State income benefit, net of federal benefit	(343,257)	(136,538)
Non-deductible loss on warrant valuation adjustment	(11,629)	199,055
Income (loss) from foreign subsidiaries	6,699	(34,552)
Change in valuation allowance	2,538,067	(9,841,464)
Tax reform rate adjustment	-	11,827,143
Other	252,713	(75,366)
Income tax expense (benefit)	$-	$-

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2018 and 2017 are as follows:

	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$21,320,935	$19,406,373
Net operating loss carryforwards - foreign	16,551	139,675
Excess of tax basis over book value of property and equipment	(2,229)	6,978
Excess of tax basis over book value of intangible assets	146,943	220,180
Stock-based compensation	1,520,209	906,526
Accrued employee compensation	83,393	-
Captialized equity costs	49,471	49,471
Inventory reserve	29,510	17,962
	23,164,783	20,747,165
Valuation allowance	(23,164,783)	(20,747,165)

Net deferred tax assets	$-	$-

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
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21.
Income taxes (continued)

The federal and state net operating loss carryforwards of approximately $77.9M from years ending December 31, 2005 through December 31, 2017 will begin to expire in 2025. The federal and state net operating loss carryforward for the year ended December 31, 2018 of $8.3M will not expire. The foreign net operating loss carryforward at December 31, 2018 of $86K will begin to expire in 2024.

22.
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.

23.
Subsequent events

The Company evaluates events that occur after the year-end date through the date the financial statements are available to be issued.

Cashless Warrant Exercise

Subsequent to December 31, 2018, the Company issued 704,108 shares of common stock upon the exercise of 1,313,258 Class N Warrants and Class L Warrants to purchase shares of stock under the terms of the respective warrant agreements.

Warrant Exercise

Subsequent to December 31, 2018, the Company issued 3,953,334 shares of common stock upon the exercise of 3,953,334Class L Warrants and Class O Warrants to purchase shares of stock under the terms of the respective warrant agreements.

Short term notes payable

Subsequent to December 31, 2018, the Company entered into short term notes payable with individuals in the total principal amount of $965,000 with an interest rate of 10% per annum. The principal and accrued interest are due and payable six months from the date of issuance or receipt of notice of warrant exercise.

Contractual Obligations

On January 2, 2019, we entered into a second amendment to the lease agreement for an additional 2,297 square feet of office space for office space which expires on December 31, 2021.

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 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, 2018. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not operating effectively as of December 31, 2018. 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."

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) for the Company. 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 U.S. GAAP.

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 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, 2018. 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 three material weaknesses in our internal control over financial reporting process. The first material weakness is due to the lack of internal expertise and resources to analyze

and properly apply generally accepted accounting principles to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distribution agreements. The second material weakness is due to the lack of internal resources to analyze and properly apply generally accepted accounting principle to accounting for equity components of service agreements with select vendors. The third material weakness relates to our information technology infrastructure. This material weakness is due to cybersecurity breaches from email spoofing. As a result, management concluded that our internal control over reporting was not effective as of December 31, 2018.

Management’s Plan to Remediate Material Weaknesses

Management has developed a remediation plan to address the material weaknesses related to its processes and procedures surrounding the accounting for complex financial instruments and derivatives, accounting for complex sales distribution agreements, accounting for equity component of service agreements and ensuring that generally accepted accounting principle disclosures are complete and accurate. The remediation plan consists of, among other things, engaging a third party financial reporting consulting firm to assist the Company in its financial reporting compliance and redesigning the procedures to enhance the identification, capture, review, approval and recording of terms and components of complex financial instruments and derivatives, complex sales distribution agreements, and any equity components of service agreements as well as identify necessary disclosures. Management has engaged a third party consultant, who is a technical accounting professional, to assist us in the interpretation and application of new and complex accounting guidance. Management will continue to review and make necessary changes to the overall design of our internal control environment. These measures are intended both to address the identified material weaknesses and to enhance our overall internal control environment.

Management will develop a remediation plan to address the material weakness related to its information technology infrastructure. The remediation plan will include, but not be limited to cyber security training for all employees and redesign of procedures that cyber security breaches may impact.

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 is in the process of designing updated changes to its controls as discussed above in “Management’s Plan to Remediate Material Weaknesses.”

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	50	Director, Chairman and Chief Executive Officer
Lisa E. Sundstrom	49	Chief Financial Officer
Shri P. Parikh	47	President, Healthcare
Peter Stegagno	59	Chief Operating Officer
Iulian Cioanta, PhD	56	Chief Science and Technology Officer
John F. Nemelka	53	Director
Alan L. Rubino	64	Director
A. Michael Stolarski	48	Director
Maj-Britt Kaltoft	55	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. In November 2018, Mr. Richardson was appointed as 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.

Shri P. Parikh joined the Company as President, Healthcare in May of 2018. Mr. Parikh most recently served as Vice President, Sales and Marketing at Molnycke Health Care from April 2013 to May 2018. Prior to Molnlycke, from 2011 to 2013 Mr. Parikh was the Director of National Accounts at Stryker Corporation, a leading medical technology company with products and services in Orthopaedics, Medical and Surgical Equipment, and Neurotechnology and Spine. Mr. Parikh began his career in sales at Bristol-Myers Squibb and held various roles with increasing sales, marketing and corporate accounts responsibility at Guidant and St. Jude Medical before joining Stryker Corporation. Mr. Parikh holds a Bachelor of Arts degree in Medical Ethics and Economics from Davison College, a Master of Business Administration from Jacksonville University and an Advanced Management Program degree from the University of Chicago.

Peter Stegagno joined the Company as Vice President, Operations in March 2006. Mr. Stegagno brings to the Company sixteen years of 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 ArgoMed 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.

A. Michael Stolarski joined the Company as a member of the board of directors in April 2016. Mr. Stolarski founded Premier Shockwave, Inc. in October 2008 and has since served as its President & CEO. From 2005 to 2008, Mr. Stolarski was the Vice President of Business Development and, previously, Acting CFO of SANUWAVE, Inc. From 2001 to 2005, he was the President – Orthopedic Division and Vice President of Finance for HealthTronics Surgical Services, Inc. From 1994 to 2001, he was the CFO and Controller of the Lithotripsy Division, Internal Auditor, and Paralegal of Integrated Health Services, Inc. Mr. Stolarski brings to our board an in-depth understanding of the orthopedic and podiatric shock wave market. In addition to being a Certified Public Accountant in the state of Maryland (inactive), he holds a M.S. in Finance from Loyola College, Baltimore a B.S. in Accounting and a B.S. in Finance from the University of Maryland, College Park.

Dr. Maj-Britt Kaltoft joined the Company as a member of the board of directors in June 2017. Since January 2017, Dr. Kaltoft heads the business development and patent functions at the Danish State Serum Institute, an institution under the Danish Ministry of Health. From 2011 to 2016, she was the Vice President – Corporate Alliance Management, Licensing Director and Business Development with Novo Nordisk headquartered in Bagsvaerd, Denmark. She has obtained outstanding results in the areas of business development, licensing and alliance management in the pharmaceutical and biotech industry at Lundbeck, Nycomed, and EffRx. Dr. Kaltoft brings 20 years of international specialization in development and successful execution of business development strategies, contractual structures and alliance management within all sectors of the life science industry.

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 five members, two of whom have 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 2019.

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 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's board of directors has determined that it is currently in the best interest of the Company and its shareholders to combine the roles of chairman of the board and chief executive officer.

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 five members, two 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, Mr. Nemelka and Mr. Stolarski 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 2019.

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 John F. Nemelka (Chairperson), Kevin A. Richardson, II, and A. Michael Stolarski. Mr. Nemelka, 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 expects to add additional independent directors to the board of directors in 2019.

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 Marcum 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 Alan L. Rubino (Chairperson), Kevin A. Richardson II, A. Michael Stolarski and Maj-Britt Kaltoft. 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 expects to add additional independent directors to the board of directors in 2019.

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 Maj-Britt Kaltoft (Chairperson), 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 expects to add additional independent directors to the board of directors in 2019.

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 they receive 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 and Dr. Maj-Britt Kaltoft qualify as independent directors 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.

Except as set forth herein, 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, 2018, we have determined that our directors, officers and greater than 10% beneficial owners complied with all applicable Section 16 filing requirements. Forms 4 filed on behalf of Mr. Stolarski, Mr. Nemelka, Mr. Rubino, Mr. Richardson and Mr. Parikh were inadvertently filed late to report the grant

of stock options that occurred on September 20, 2018. A Form 3 and a Form 4 filed on behalf of Mr. Parikh on June 12, 2018 were inadvertently filed late to report his appointment and the grant of stock options that occurred on May 31, 2018. Forms 4 filed on January 19, 2018 for Mr. Stolarski, Ms. Sundstrom, Mr. Richardson, Mr. Nemelka and Mr. Rubino were inadvertently filed late to report grants of certain warrants of the Company.

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table for Fiscal Years 2018 and 2017

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, 2018 and 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(3)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II Chairman of the Board and Chief Executive Officer (principal executive officer)	2018	$235,000(1)	-	$226,600(2)	-	-	-	$2,459	$464,059
	2017	$120,000(1)	-	$130,882(2)	-	-	-	-	$250,882
Lisa E. Sundstrom Chief Financial Officer (principal financial officer)	2018	$192,917	-	$154,500(2)	-	-	-	$15,960	$363,377
	2017	$115,000	-	$88,352(2)	-	-	-	$12,652	$216,004
Shri P. Parikh President, Healthcare	2018	$182,496(4)	-	$206,000(2)	-	-	-	$10,702	$399,198
	2017	$-	-	-	-	-	-	$-	$-
Peter Stegano Chief Operating	2018	$200,000	-	$154,500(2)	-	-	-	$15,142	$369,642
	2017	$200,000	-	$88,352(2)	-	-	-	$13,498	$301,850

Officer									
Iulian Cioanta	2018	$200,000	-	$154,500(2)	-	-	-	$23,610	$378,110
Chief Science and Technology Officer	2017	$200,000	-	$88,352(2)	-	-	-	$19,583	$307,935

(1)
Mr. Richardson has been the Company's Chairman of the Board since the Company's inception. Since 2014, Mr. Richardson has also been our Acting Chief Executive Officer. We continue to compensate Mr. Richardson as a director as described in "Discussion of Director Compensation" below, however we pay him an additional $10,000 per month in recognition of his additional role as Acting Chief Executive Officer. On November 30, 2018 Mr. Richardson was named Chief Executive Officer of the Company.
(2)
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.
(3)
Includes health, dental, life and disability insurance premiums and 401(k) matching contributions.
(4)
Mr. Parikh was named President, Healthcare of the Company effective May 31,
2018.

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 35,000,000 and 22,500,000 shares of common stock reserved for grant at December 31, 2018 and 2017, respectively.

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, 2018, there were 4,628,281 shares of common stock available for grant under the Stock Incentive Plan. For the years ended December 31, 2018 and 2017, there were 6,350,000 and 2,700,000 options, respectively, granted to the Company's executive officers under the Stock Incentive Plan.

Outstanding Equity Awards at 2018 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2018.

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	452,381(3)	-	-	$0.11	10/1/2025	-	-	-	-
Chief Executive Officer	297,619(3)	-	-	$0.06	10/1/2025	-	-	-	-
(principal executive officer)	700,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	594,300(5)	-	-	$0.18	11/9/2026	-	-	-	-
	900,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	640,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
	1,100,000(8)	-	-	$0.21	9/20/2028	-	-	-	-
Lisa Sundstrom	65,000(1)	-	-	$0.35	02/21/2023	-	-	-	-
Chief Finanical Officer	25,000(2)	-	-	$0.55	5/7/2024	-	-	-	-
(principal financial	301,587(3)	-	-	$0.11	10/1/2025	-	-	-	-

officer)									
	198,413(3)	-	-	$0.06	10/1/2025	-	-	-	-
	500,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	424,500(5)	-	-	$0.18	11/9/2026	-	-	-	-
	600,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	440,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
	750,000(8)	-	-	$0.21	9/20/2028	-	-	-	-
Shri Parikh	2,000,000(9)	-	-	$0.42	5/31/2028	-	-	-	-
President, Healthcare	1,000,000(8)	-	-	$0.21	9/20/2028	-	-	-	-
Peter Stegano	333,644(1)	-	-	$0.35	02/21/2023	-	-	-	-
Chief Operating Officer	50,000(2)	-	-	$0.55	5/7/2024	-	-	-	-
	301,587(3)	-	-	$0.11	10/1/2025	-	-	-	-
	198,413(3)	-	-	$0.06	10/1/2025	-	-	-	-
	500,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	424,500(5)	-	-	$0.18	11/9/2026	-	-	-	-
	600,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	440,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
	750,000(8)	-	-	$0.21	9/20/2028	-	-	-	-
Iulian Cioanta	296,241(1)	-	-	$0.35	02/21/2023	-	-	-	-
Chief Science and Technology Officer	50,000(2)	-	-	$0.55	5/7/2024	-	-	-	-
	301,587(3)	-	-	$0.11	10/1/2025	-	-	-	-
	198,413(3)	-	-	$0.06	10/1/2025	-	-	-	-
	500,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	424,500(5)	-	-	$0.18	11/9/2026	-	-	-	-
	600,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	440,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
	750,000(8)	-	-	$0.21	9/20/2028	-	-	-	-

(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 all options which were previously granted to Mr. Richardson, Ms. Sundstrom, Mr. Stegagno and Dr. Cioanta. The Company granted Mr. Richardson 115,000 options, Ms. Sundstrom 65,000 options, Mr. Stegagno 333,644 options and Dr. Cioanta 296,241 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, Mr. Stegagno 50,000 options and Dr. Cioanta 50,000 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, Ms. Sundstrom 500,000 options, Mr. Stegagno 500,000 options and Dr. Cioanta 500,000 options on October 1, 2015 which vests at grant date.
(4)

The Company granted Mr. Richardson 700,000 options, Ms. Sundstrom 500,000 options, Mr. Stegagno 500,000 options and Dr. Cioanta 500,000 options on June 16, 2016 which vests at grant date.

(5)

The Company granted Mr. Richardson 594,300 options, Ms. Sundstrom 424,500 options, Mr. Stegagno 424,500 options and Dr. Cioanta 424,500 options on November 9, 2016 which vests at grant date.

(6)

The Company granted Mr. Richardson 900,000 options, Ms. Sundstrom 600,000 options, Mr. Stegagno 600,000 options and Dr. Cioanta 600,000 options on June 15, 2017 which vests at grant date.

(7)

The Company granted Mr. Richardson 640,000 warrants, Ms. Sundstrom 440,000 warrants, Mr. Stegagno 440,000 warrants and Dr. Cioanta 440,000 warrants on Deccember 11, 2017 which vests at grant date.

(8)

The Company granted Mr. Richardson 1,100,000 options, Ms. Sundstrom 750,000 options, Mr. Parikh 1,000,000 options, Mr. Stegagno 750,000 options and Dr. Cioanta 750,000 options on September 20, 2018 which vests at grant date.

(9)

The Company granted Mr. Parikh 2,000,000 options on May 31, 2018 which vests at grant date.

Director Compensation Table for Fiscal Year 2018

The following table provides certain information concerning compensation for each director during the fiscal year ended December 31, 2018.

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)	$40,000	-	$226,600	-	-	-	$266,600
John F. Nemelka	$40,000	-	$72,100	-	-	-	$112,100
Alan L. Rubino	$40,000	-	$72,100	-	-	-	$112,100
A. Michael Stolarski	$40,000	-	$72,100	-	-	-	$112,100
Maj-Britt Kaltoft	$40,000	-	$72,100	-	-	-	$112,100

(1)
Mr. Richardson has been the Company's Chairman of the Board since the Company's inception. Since 2014, Mr. Richardson has also been our Acting Chief Executive Officer. We continue to compensate Mr. Richardson as a director as described in "Discussion of Director Compensation" below, however we pay him an additional $10,000 per month in recognition of his additional role as Acting Chief Executive Officer. On November 30, 2018 Mr. Richardson was named Chief Executive Officer of the Company.

Discussion of Director Compensation

Effective January 1, 2018, the Company began to compensate its directors at an annual rate of $40,000 each. On September 20, 2018, the Company issued an option to purchase 1,100,000 shares of the Company’s common stock at $0.21 per share to non-employee director Kevin A. Richardson II and the Company issued options to purchase 350,000 shares of the Company’s common stock at $0.21 per share to non-employee directors John F. Nemelka, Alan L. Rubino, A. Michael Stolarski and Maj-Britt Kaltoft. On June 15, 2017, the Company issued an option to purchase 900,000 shares of the Company’s common stock at $0.11 per share to non-employee director Kevin A. Richardson II and the Company issued options to purchase 300,000 shares of the Company’s common stock at $0.11 per share to

non-employee directors John F. Nemelka, Alan L. Rubino, A. Michael Stolarski and Maj-Britt Kaltoft. On November 9, 2016, the Company issued an option to purchase 594,300 shares of the Company's common stock at $0.18 per share to director Kevin A. Richardson, II and the Company issued options to purchase 169,800 shares of the Company's common stock at $0.18 per share to directors John F. Nemelka, Alan L. Rubino and A. Michael Stolarski. On June 16, 2016, the Company issued an option to purchase 700,000 shares of the Company's common stock at $0.04 per share to director Kevin A. Richardson, II and the Company issued options to purchase 200,000 shares of the Company's common stock at $0.04 per share to directors John F. Nemelka, Alan L. Rubino and A. Michael Stolarski. On October 1, 2015, the Company issued an option to purchase 452,381 shares of the Company's common stock at $0.11 per share and an option to purchase 297,619 shares of the Company's common stock at $0.50 per share to director Kevin A. Richardson, II and the Company issued options to purchase 150,795 shares of the Company's common stock at $0.11 per share and options to purchase 99,205 shares of the Company's common stock at $0.50 per share to directors John F. Nemelka and Alan L. Rubino. The options above issued at $0.50 per share were re-priced to $0.06 per share in March 2016 as the result of the public offering. On September 3, 2013, the Company issued an option to purchase 100,000 shares of the Company's common stock at $0.65 per share to 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 options to purchase 15,000 shares of the Company's Common Stock and were each issued options to purchase 115,000 shares of the Company's Common Stock at an exercise price of $0.35 per share.

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, 2018: Kevin A. Richardson, II – 4,159,300, John F. Nemelka – 1,384,800, Alan L. Rubino – 1,369,800, A. Michael Stolarski – 1,019,800 and Maj-Britt Kaltoft – 650,000.

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

The following table sets forth certain information, as of March 28, 2019, 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 named 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	Percent of Shares Outstanding (2)
Kevin A. Richardson II (4)	17,564,160	10.6%
A. Michael Stolarski (3)	16,789,333	9.9%
Peter Stegagno (5)	4,261,780	2.7%
Iulian Cioanta (6)	3,576,146	2.2%
Lisa E. Sundstrom (7)	3,304,500	2.1%
John F. Nemelka (8)	1,596,055	1.0%
Alan Rubino (9)	1,569,800	1.0%
Maj-Britt Kaltoft (10)	850,000	0.5%
All directors and executive officers as a group (8 persons)	49,511,774	30.0%
5% Beneficial Owner:		
Jerome Gildner (11)	13,333,334	8.2%
John McDermott (11)	12,575,756	7.7%
Nicholas Carosi III (11)	11,818,182	7.2%
James McGraw (11)	11,610,694	7.1%

(1)
Unless otherwise noted, each beneficial owner has the same address as us.
(2)
Applicable percentage ownership is based on 160,322,580 shares of common stock outstanding as of March 28, 2019, "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 28, 2019. 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 1,019,800 shares of common stock, warrants to purchase up to 7,499,452 shares of common stock and 4,545,455 common shares available upon conversion of convertible promissory note.
(4)

Includes options to purchase up to 4,159,300 shares of common stock, warrants to purchase up to 3,222,583 shares of common stock and 2,363,636 common shares available upon conversion of convertible promissory note. In addition, this amount includes 138,782 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.

(5)

Consists of options to purchase up to 3,158,144 shares of common stock, warrants to purchase up to 771,818 shares of common stock and 331,818 common shares available upon conversion of convertible promissory note.

(6)

Consists of options to purchase up to 3,120,741 shares of common stock and warrants to purchase up to 440,000 shares of common stock.

(7)

Consists of options to purchase up to 2,864,500 shares of common stock and warrants to purchase up to 440,000 shares of common stock.

(8)

Includes options to purchase up to 1,384,800 shares of common stock and warrants to purchase up to 200,000 shares of common stock.

(9)

Includes options to purchase up to 1,369,800 shares of common stock and warrants to purchase up to 200,000 shares of common stock.

(10)

Includes options to purchase up to 650,000 shares of common stock and warrants to purchase up to 200,000 shares of common stock.

(11)

Based on records of the Company.

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, since January 1, 2017, there have been no transactions with related persons required to be disclosed in this report.

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation (“PSWC”), and Premier Shockwave, Inc., a Georgia Corporation (“PS”). Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. The agreement provides for the purchase by PSWC and PS of dermaPACE System and related equipment sold by the Company and includes a minimum purchase of 100 units over 3 years. The agreement grants PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. Under the agreement, the Company is responsible for the servicing and repairs of such dermaPACE Systems and equipment. The agreement also contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. The agreement also contains certain transfer restrictions on the stock of PSWC.

On December 29, 2017, the Company entered into a line of credit agreement with A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand. The outstanding balance as of December 31, 2017 with accrued interest was $370,179 and $0 interest was paid for the period ending December 31, 2017.

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder.

On December 11, 2017, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000 shares of common stock at an exercise price of $0.11 per share. On March 1, 2019, the Company amended the expiration date of the Class O Warrants from March 17, 2019 to June 28, 2019 to be effective on March 1, 2019. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company’s board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company’s board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants.

On March 27, 2017, the Company began offering subscriptions for 10% convertible promissory notes (the “10% Convertible Promissory Notes”) to selected accredited investors. The 10% Convertible Promissory Notes include a warrant agreement (the “Class N Warrant Agreement”) to purchase Common Stock equal to the amount obtained by

dividing the (i) sum of the principal amount, by (ii) $0.11. The Class N Warrant Agreement expires March 17, 2019. On January 23, 2019, the Company amended the expiration date of the Class N Warrants from March 17, 2019 to May 1, 2019, effective as of January 23, 2019. On March 1, 2019, the Company amended the expiration date of the Class N Warrants from March 17, 2019 to June 28, 2019 to be effective on March 1, 2019. A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $330,000. A. Michael Stolarski and Kevin A. Richardson II, both members of the Company's board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The 10% Convertible Promissory Notes associated with these subscriptions were issued in January 2018.

Director Independence

Our board of directors has determined that Alan L. Rubino and Maj-Britt Kaltoft qualify as independent directors based on the Nasdaq stock market definition of “independent director.” Our board of directors has determined that our other three directors, Kevin A. Richardson II, John F. Nemelka and A. Michael Stolarski, 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 prior principal independent registered public accounting firm, Cherry Bekaert LLP, for the years ended December 31, 2018 and 2017 and audit and other services provided by our current principal independent registered public accounting firm, Marcum LLP for the year ended December 31, 2018:

Fee Category	2018	2017
Audit fees	$226,000	$199,620
Tax fees	18,000	21,600
All other fees	-	-
Total fees	$244,000	$221,220

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 2018 and the first quarter of 2019, 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 2018, 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 2018.

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. 1301, 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 2018 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, 2018 be included in the Company's Annual Report on Form 10-K, for filing with the SEC.

The Audit Committee

John F. Nemelka (Chair)
Kevin A. Richardson II
A. Michael Stolarski

April 1, 2019

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 in Item 8 of Part II:

	Page
Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2018 and 2017	F-3
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018 and 2017	F-4
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2018 and 2017	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017	F-5
Notes to Consolidated Financial Statements	F-7

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 below are furnished or filed and, as applicable, are incorporated by reference herein as part of this Annual Report on Form 10-K.

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 (Incorporated by reference to the Form 10-K filed with the SEC on March 30, 2016).
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible
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 the Company 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	Amendment No. 1 to Class K Warrant Agreement by and between the Company and HealthTronics, Inc., dated June 28, 2016 (Incorporated by reference to the Form 10-Q filed with the SEC on August 15, 2016).
4.12	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).
4.13	Second Form of Class L Warrant Common Stock Purchase Warrant (Incorporated by reference to the Form 8-K filed with the SEC on August 24, 2016).
4.14	Registration Rights Agreement dated January 13, 2016 among the Company and the investors listed therein (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
4.15	Class K Warrant Agreement dated as of August 3, 2017, between the Company and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
4.16	

	Form of Class N Warrant. (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
4.17	Letter to Series A Warrantholders, Class N Warrantholders and Class L Warrantholders, dated January 29, 2019. (Incorporated by reference to Form 8-K filed with the SEC on January 25, 2019).
4.18	Form of Class O Warrant. (Incorporated by reference to Form 8-K filed with the SEC on March 15, 2019).
4.19	Letter to Class N Warrantholders and Class O Warrantholders, dated March 14, 2019. (Incorporated by Reference to Form 8-K filed with the SEC on March 15, 2019).
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).
10.7	Exchange Agreement dated January 13, 2016 among the Company and the investors listed therein (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
10.8	Escrow Deposit Agreement dated January 25, 2016 among the Company, Newport Coast Securities, Inc. and Signature Bank (Incorporated by reference to the Form S-1/A filed with the SEC on February 3, 2016).
10.9	Second Amendment to Certain Promissory Notes entered into as of June 28, 2016 by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to the Form 10-Q filed with the SEC on August 15, 2016).
10.10	Form of Securities Purchase Agreement, by and among the Company and the accredited investors a party thereto, dated March 11, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on March 17, 2016).
10.11	Form of Securities Purchase Agreement, by and between the Company and the accredited investors a party thereto, dated August 24, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on J August 25, 2016).
10.12	Form of Registration Rights Agreement, by and between the Company and the holders a party thereto, dated August 24, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on August 25, 2016).
10.13	Third Amendment to promissory notes entered into as of August 3, 2017 by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
10.14#	Binding Term Sheet for Joint Venture Agreement between the Company and MundiMed Distribuidora Hospitalar LTDA effective as of September 25, 2017 (Incorporated by reference to Form 10-Q filed with the SEC on November 15, 2017).
10.15	Form of 10% Convertible Promissory Note, by and among the Company and the accredited investors a party thereto. (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
10.16	Form of Registration Rights Agreement, by and among the Company and the accredited investors a party thereto (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
10.17#	Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs of dermaPACE Systems and Equipment among the Company, and Premier Shockwave Wound Care, Inc. and Premier Shockwave, Inc. dated as of February 13, 2018. (Incorporated by reference to Form 10-K filed with the SEC on March 29, 2018).
10.18	Agreement, dated June 14, 2018, by and among the Company and Johnfk Medical Inc. (Incorporated by reference to Form 8-K filed with the SEC on June 29, 2018).
10.19	Joint Venture Agreement, dated September 21, 2018, by and among the Company, Johnfk Medical Inc. and Holistic Health Institute Pte. Ltd. (Incorporated by reference to Form 8-K filed with the SEC on September 27, 2018).
10.20	Master Equipment Lease, dated January 26, 2018, by and among the Company and NFS Leasing, Inc. (Incorporated by reference to Form 8-K filed with the SEC on February 15, 2018).
10.21	Offer Letter, dated as of November 30, 2018, by and between SANUWAVE Health, Inc. and Kevin Richardson. (Incorporated by reference to Form 8-K filed with the SEC on December 4, 2018).
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	Offer Letter, dated as of April 15, 2018, by and between SANUWAVE Health, Inc., and Shri Parikh. (Incorporated by reference to Form 8-K filed with the SEC on June 7, 2018).
14.1	Code of Business Conduct and Ethics of SANUWAVE Health, Inc. (Incorporated by reference to the Form 10-K filed with the SEC on March 30, 2016).
21.1*	List of subsidiaries
23.1*	Consent of Cherry Bekaert LLP, independent registered public accountants.
23.2*	Consent of Marcum LLP, independent registered public accountants.
24.1*	Power of Attorney (included on signature page).
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

Indicates management contract or compensatory plan or arrangement.
* Filed herewith
# Confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and
submitted separately to the Securities and Exchange Commission.
** 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.

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

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: April 1, 2019 By: /s/ Kevin A. Richardson, II
Name: Kevin A. Richardson, II
Title: Acting Chief Executive Officer

POWER OF ATTORNEY

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Kevin A. Richardson, II and Lisa E. Sundstrom, and each of them, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or such person's substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

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:

Signature	Title	Date
/s/ Kevin A. Richardson, II Name: Kevin A. Richardson, II	Acting Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	April 1, 2019
/s/ Lisa E. Sundstrom Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	April 1, 2019
/s/ John F. Nemelka Name: John F. Nemelka	Director	April 1, 2019
/s/ Alan L. Rubino Name: Alan L. Rubino	Director	April 1, 2019
/s/ A. Michael Stolarski Name: A. Michael Stolarski	Director	April 1, 2019
/s/ Maj-Britt Kaltoft Name: Maj-Britt Kaltoft	Director	April 1, 2019

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