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.

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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.

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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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Consolidated Financial Statements

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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