SANUWAVE Health, Inc.
Form 10-K
March 14, 2012
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

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

For the transition period from _____ to

Commission File Number 000-52985

SANUWAVE Health, Inc.
(Exact name of registrant as specified in its charter)

Nevada	20-1176000
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11680 Great Oaks Way, Suite 350 Alpharetta, GA	30022
(Address of principal executive offices)	(Zip Code)

(770) 419-7525
(Registrant's telephone number, including area code)

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

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

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

Common Stock, $0.001 par value per share

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes o 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. x

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes x 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, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was $20.6 million.

As of March 9, 2012, there were issued and outstanding 20,907,536 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, 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 an emerging global regenerative medicine company focused on the development and commercialization of noninvasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. Our portfolio of 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 are focused on developing our Pulsed Acoustic Cellular Expression (PACE®) technology to activate healing in:

- wound conditions, including diabetic foot ulcers, venous ulcers, pressure sores, burns and other skin eruption conditions;
- orthopedic/spine applications, such as eliminating chronic pain in joints from trauma or arthritis, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;
- plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and
- cardiac applications for removing plaque due to atherosclerosis and improving heart muscle performance.

dermaPACE – Our lead product candidate

Our lead device product for the global wound care market, dermaPACE®, has received the European Conformity Marking ("CE Mark") allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue, and has completed its pivotal Phase III, Investigational Device Exemption ("IDE") trial in the United States for the treatment of diabetic foot ulcers. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to Sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and Sham-control at 12 weeks in the Intent-to-Treat ("ITT") population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) Sham-control subjects.

- In addition to the originally proposed 12-week efficacy analysis, the United States Food and Drug Administration (the "FDA") expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete

wound closure compared with 23% of Sham-control subjects (p=0.047); in the Efficacy Evaluable ("EE") population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of Sham-control subjects (p=0.018); at 24 weeks dermaPACE achieved 40% complete wound closure in the ITT population (p=0.054) and 41% complete wound closure in the EE population (p=0.022).

- Subjects treated with dermaPACE achieved a significant increase in the rate of complete wound closure or ≥90% wound area reduction by or at 12 weeks ($p<0.05$).

- Within 6 weeks following the initial dermaPACE procedure, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive Sham-control ($p<0.05$).

- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20% in the Sham-control group.

- Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the Sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

We filed with the FDA the third and final module of the dermaPACE Premarket Approval ("PMA") application in June 2011. In December 2011, we received a major deficiency letter from the FDA regarding the FDA's review of the dermaPACE PMA. The FDA issues a major deficiency letter to the applicant when the PMA lacks significant information necessary for the FDA to complete its review or to determine whether there is reasonable assurance that the device is safe and effective for its intended use. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's previously disclosed failure to meet the study's primary endpoint of 100% wound closure compared with Sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency is for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We have evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we now expect to conduct additional clinical work to provide support for the FDA to approve the dermaPACE PMA. We have finalized our clinical study plan and submitted our IDE supplement for conditional approval to the FDA in March 2012. At a minimum, we expect the additional clinical work to take up to 24 months before completion and submission to the FDA. Therefore, in 2012 we have taken meaningful cost cutting measures to reduce our monthly cash needs. In addition, we have formed a special committee of our board of directors who have retained Canaccord Genuity Inc., a leading investment bank, to explore capital fund raising and/or strategic options to fund us while we complete this additional clinical work.

We have received two Category III Current Procedural Terminology ("CPT") codes for Extracorporeal Shockwave Technology ("ESWT") in wound healing. CPT Category III codes are a set of tracking codes established by the American Medical Association ("AMA") that permit data collection for emerging technology, services and procedures. Pending approval by the FDA of our PMA application, the dermaPACE would be the first and only ESWT device in the United States capable of utilizing these codes.

There are also billing codes that facilities, not 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 Ambulatory Payment Classification ("APC") groups based on internal available information. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment. Information on the clinical similarities of ESWT services within the Hospital Outpatient Prospective System ("OPPS") as well as costs will be provided to the Centers for Medicare & Medicaid Services.

Prior to receiving FDA approval, we intend to begin the process of initiating private industry payor meetings in the United States to introduce the economics and positive efficacy results of dermaPACE. These discussions will focus on building knowledge of dermaPACE and educating to the positive value proposition compared to existing alternatives. We believe that, in addition to improving the quality of life of the patients treated, dermaPACE will provide cost benefits to payors, employers and society as a whole through improved healing, shortened healing times, and fewer and less burdensome required procedures.

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

Pulsed Acoustic Cellular Expression (“PACE”) Technology

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 which are designed to promote angiogenic and positive inflammatory responses, and quickly initiate the healing cascade. This is thought to result in microcirculatory improvement, including increased perfusion and blood vessel widening (arteriogenesis), the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE procedures trigger the initiation of an accelerated inflammatory response that speeds wounds into proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help reinitiate the body’s own healing response. We believe that our PACE technology is well suited for various applications due to its activation of a broad spectrum of cellular events critical for the initiation and progression of healing.

High-energy, acoustic pressure waves in the shockwave spectrum are the primary component of our previously developed product, Ossatron®, which was approved by the FDA and marketed in the United States for use in chronic tendonitis of the foot in 2000 and the elbow in 2003. Additionally, acoustic shockwaves have been used safely at much higher energy and pulse levels in the lithotripsy procedure (breaking up kidney stones) by urologists for over 20 years and has reached standard of care status.

We research, design, manufacture, market and service our products worldwide and believe we have already demonstrated that our technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved Ossatron device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our Ossatron, Evotron®, and more recently introduced orthoPACE® devices in Europe.

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, as well as the development of next generation devices utilizing our PACE technology to maximize healing response and intervention.

Currently, there are limited biological or mechanical therapies to activate the healing and regeneration of tissue, bone and vascular structures. As baby boomers age, the incidence of their targeted diseases and musculoskeletal injuries and ailments will be far more prevalent. We believe that our studies suggest that our PACE technology will be effective in our target applications. If successful, we anticipate that these clinical studies should lead to regulatory approval of our regenerative product candidates in the United States, Europe and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and noninvasive treatment options in wound healing, orthopedic/spine injuries, plastic/cosmetic uses and cardiac procedures, improving the quality of life for millions of patients suffering from injuries or deterioration of tissue, bones and vascular structures.

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Our primary interest is developing our lead product candidate, dermaPACE, for the global wound care market, with the first focus in the United States on diabetic foot ulcers. Diabetes is common, disabling and deadly. In the United States, diabetes has reached epidemic proportions. According to the American Diabetes Association, about 25.8 million people (8.3% of the total United States population) have diabetes, and nearly two million new cases are diagnosed in people aged 20 years or older each year. If current trends continue, 1 in 3 Americans will develop diabetes at some point in their lifetime, and those with diabetes will lose, on average, 10-15 years of life expectancy.

Importantly, up to 25% of people with diabetes will develop a diabetic foot ulcer, resulting in 3 million diabetic foot ulcers annually in the United States alone. More than half of all foot ulcers will become infected, thus requiring hospitalization, and 1 in 5 will require an amputation that carries a high risk of mortality. Diabetes puts tremendous economic pressure on the United States healthcare system. In January 2011, the Centers for Disease Control and Prevention (the "CDC") reported the total costs (direct and indirect) of diabetes in the United States is $174 billion annually, and people with diagnosed diabetes have medical expenditures that are over two times higher than medical expenditures for people without diabetes. Hospitalization costs alone are $16,000 to $20,000 for a patient with a diabetic foot ulcer, and direct and indirect costs of an amputation range from $20,000 to $60,000 per patient. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need globally, yet in short supply. According to the American Diabetes Association, by the year 2025 the prevalence of diabetes is expected to rise by 72% to 324 million people worldwide.

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

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

Developing Product Opportunities - Orthopedic and Spine

We launched in Europe the orthoPACE device which is intended for use in orthopedic, trauma and sports medicine indications following CE Mark approval in June 2010. The device features a new, 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 will initially be used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs.

We believe there are significant opportunities in the worldwide orthopedic and spine markets, driven by aging baby boomers, the desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

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

Trauma injuries are acute and result from any physical damage to the body caused by violence or accident or fracture. Surgical treatment of traumatic fractures often involves fixation with metallic plates, screws and rods (internal fixation) and include off-loading to prevent motion, permitting the body to initiate a healing response. In the United States, six million traumatic fractures are treated each year, and over one million internal fixation procedures are performed annually. The prevalence of non-union among these fractures is between 2.5% and 10.0% depending on the fracture type and risk factors such as diabetes and smoking history or other systemic diseases. At the time of surgery,

adjunctive agents (such as autograft, cadaver bone and synthetic filling materials) are often implanted along with internal fixation to fill bony gaps or facilitate the healing process to avoid delayed union or non-union (incomplete fracture healing) results. Both pre-clinical and clinical investigations have shown positive results, suggesting our technology could potentially be developed as an adjunct to these surgeries or primary treatment protocol for delayed or non-union events.

Spinal fusion is a surgical technique performed to correct an unstable part of the spine, resulting from certain conditions such as degenerative disc disease ("DDD"), by joining two or more vertebrae, which can no longer be managed with conservative methods. There are over 500,000 spinal fusions performed in the United States annually on vertebrae of the lower back (lumbar) or neck region (cervical). Orthopedic surgeons often will take bone from another part of the body (i.e. hip), known as autograft, and use it to fill the space between adjacent vertebrae. However, some disadvantages include the need to perform a second surgery, additional operative time, the potential for post-operative complications and long-term pain at the graft site. Bone morphogenetic proteins ("BMPs") have also been used as a replacement for autograft in spinal fusion surgery; however, they have been associated with some potentially severe side effects, particularly when used in the neck region.

Market Trends

We are focused on the development of products that have the potential to address substantial unmet clinical needs across broad market indications. We believe there are limited therapeutic treatments that directly and reproducibly activate healing processes in the areas in which we are focusing, particularly for wound care and repair of certain types of musculoskeletal conditions.

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

With the success of negative pressure wound therapy devices in the wound care market over the last decade and the recognition of the global epidemic associated with certain types of wounds, as well as deteriorating musculoskeletal conditions attributed to various disease states such as obesity, diabetes and ischemia due to vascular and heart disease, as well as sports injuries, we believe that Medicare and private insurers have become aware of the costs and expenditures associated with the adjunctive therapies being utilized for wound healing and orthopedic/spine conditions with limited efficacies in full skin closure, or bone and tissue regeneration. We believe the wound healing and orthopedic markets are undergoing a transition, and 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 objective is to be a leader in the development and commercialization of novel, biological response activating devices to treat tissue, musculoskeletal and vascular structure conditions. Our main vehicle for growth is the development and commercialization of our PACE technology. Our immediate goal 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:

- Develop and commercialize noninvasive biological response activating devices in the regenerative medicine area that are superior to current medical devices for the treatment of tissue, musculoskeletal and vascular structures.

We intend to use our proprietary technologies and know-how in the use of high-energy, acoustic pressure waves in the shockwave spectrum to address unmet medical needs in wound care, orthopedic/spine, plastic/cosmetic and cardiac indications.

- Focus on products with a cost-effective time to market that utilize our experiences and track record in product approvals.

We have a track record of developing products by relying on our products that have been previously authorized for marketing by the FDA and by leveraging the lessons learned from those previous experiences as the cornerstone for further development and regulatory approvals. We will seek to repeat this process of utilizing FDA-cleared or approved components in our subsequent product candidates. However, we cannot be certain that this strategy will accelerate the regulatory approval process for our product candidates, or that we will obtain such approval.

- Leverage our historical data and experience to accelerate the development of our lead wound care product candidate, as well as additional product candidates, for our target markets.

We believe the ability of our legacy products, such as Ossatron, to safely stimulate and reestablish normal healing in chronic conditions indicates the potential successful use of dermaPACE and our other product candidates to stimulate and reinstitute the normal healing process through angiogenesis. We believe that much of the data and experience generated as part of the clinical development will be useful in gaining the required approval of our product candidates, including product manufacturing procedures and records, stability test results, analytical test methodology, pre-clinical and human safety test results, and, potentially, efficacy information.

- Maximize the value of our PACE product candidates through control of distribution channels.

In the United States, we plan to build a direct sales force managed by an in-house sales management team and supported by employee product specialists. As a result of our prior product approvals, we have spent significant resources on training and educating specialists in the use of our technology. We believe that this approach will allow us to have an immediate impact in the market by leveraging existing physician relationships. Outside the United States, we intend to utilize our distributor relationships for product introduction and adoption in local markets.

- Support the clinical affairs activities for payment and reimbursement for our globally approved products and product candidates.

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 many countries, we may be required to produce clinical data, which may involve more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies.

Scientific Advisors

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

We pay consulting fees to 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 and reimbursements of $37,500 and $90,126 for the years ended December 31, 2011 and 2010, respectively.

Sales, Marketing and Distribution

We intend to establish a direct sales force in the wound care market that will market our products in the United States. The direct sales force will be managed by an in-house sales management team and supported by product specialists employed by us who will train the sales force and provide product education for our physician and care giver customers.

Outside the United States, we intend to employ distributors to represent our products in our respective international markets. These distributors will be 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. In addition, we will rely on these distributors to manage physical distribution, customer service and billing services for our international customers.

Manufacturing

We have developed a network of suppliers, manufacturers and contract service providers to provide sufficient quantities of our products and product candidates through the development and clinical testing 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 products and product candidates. Our generator boxes are manufactured in accordance with applicable quality standards (EN ISO 13485) and applicable industry and regulatory standards. We produce the applicators and applicator kits for our products. In addition, we program and load software and perform the final product testing and certifications internally for all of our devices.

Our two facilities in Alpharetta, Georgia consist of approximately 20,000 square feet in total, and provide office, research and development, quality control, production and warehouse space. They are FDA registered facilities and are ISO 13485 certified.

Intellectual Property

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

Patents

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

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

We are the assignee of eighteen (18) issued United States patents and nine (9) issued foreign patents. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations, piezoelectric fiber shockwave devices, chemical components for shockwave generation and detachable therapy heads with data storage. Our United States patents also include patent claims directed to methods of using acoustic shockwaves, including shockwave devices such as our products, to treat ischemic conditions, spinal cord scar tissue and spinal injuries, body tissues under positive pressure, bone surface gaps, and, within particular treatment parameters, diabetic foot ulcers and pressure sores. While such patented method claims may provide patent protection against certain indirect infringing promotion and sales activities of competing manufacturers and distributors, certain medical methods performed by medical practitioners or related health care entities may be subject to exemption from potential infringement claims under 35 U.S.C. § 287(c) and, therefore, may limit enforcement of claims of our method patents as compared to device and non-medical method patents.

We also currently maintain nine (9) United States non-provisional applications and ten (10) foreign patent applications. Our patent-pending rights include inventions directed to certain shockwave devices and systems, ancillary products and components for shockwave treatment devices, and various methods of using acoustic pressure waves. Such patent-pending methods include, for example, using acoustic pressure waves to treat soft tissue disorders, bones, joints, wounds, skin, blood vessels and circulatory disorders, lymphatic disorders, cardiac tissue, fat and cellulite, cancer, blood and fluids for sterilization, and to destroy pathogens. All of our United States and foreign pending applications either have yet to be examined or require response to an examiner's office action rejections and, therefore, remain subject to further prosecution, the possibility of further rejections and appeals, and/or the possibility we may elect to abandon prosecution, without assurance that a patent may issue from any pending application.

Under our license to HealthTronics, we reserve exclusive rights in our purchased portfolio as to orthopedic, tendonopathy, skin wounds, cardiac, dental and neural medical conditions and to all conditions in animals (the "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 (the "Litho Field"). HealthTronics also receives non-exclusive and non-sublicensable rights in the purchased portfolio as to any products in all fields other than the Ortho Field and Litho Field.

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

A Switzerland based company, SwiTech Medical AG ("SwiTech"), filed an ex parte reexamination request on March 23, 2010, against United States Pat. No. 6,972,116 which was assigned by HealthTronics to us on August 30, 2011. On February 14, 2012, we filed an appeal against rejections that all pending claims of the 6,972,116 patent were obvious in view of newly cited prior art. If the patent claims are finally rejected by the United States Patent & Trademark Office (the "USPTO"), we will continue to be able to use the patented materials in our devices. While the ultimate outcome of this matter is not presently determinable, it is the opinion of management that the resolution will not have a material adverse effect on the financial position or results of operations of the Company.

SwiTech filed an ex parte reexamination request on July 15, 2010, against our United States Pat. No. 6,080,119. The USPTO granted the request with a non-final examiner's office action rejecting the issued patent claims as anticipated and obvious over newly cited art. After the reexamination, the USPTO issued a reexamination certificate upholding ten amended claims of our patent.

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

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

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

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

Trademarks

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

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

We have filed pending trademark applications for: dermaPACE™ (Canada), angioPACE™ (United States), PACE™ (Canada) 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® (United States, Germany and Switzerland), Evotrode® (Germany and Switzerland), HMT® (Switzerland), Orthotripsy® (United States), Reflectron® (Germany and Switzerland), Reflectrode® (Germany and Switzerland), CSWT® (Switzerland), OSWT® (Switzerland) and TSWT® (Switzerland).

Potential Intellectual Property Issues

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

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

For additional risks related to our intellectual property, see “Risk Factors - Risks Related to Intellectual Property.”

Competition

We believe the advanced wound care market can benefit from our solution which up-regulates the biological factors that promote wound healing. Current technologies developed by Kinetic Concepts, Inc. (“KCI”), Advanced BioHealing, Inc. (acquired by Shire plc in 2011), Organogenesis, Inc., Smith & Nephew plc, Integra LifeSciences Holdings Corporation and Systagenix Wound Management (US), Inc. manage wounds, but, in our opinion, do not provide the value proposition to the patients and care givers like our PACE technology has the potential to do. The leading medical device serving this market is the Vacuum Assisted Closure (“V.A.C.”) System marketed by KCI. The V.A.C. is a negative pressure wound therapy (“NPWT”) device that applies suction to debride and better manage wounds. KCI successfully launched the V.A.C. in the United States to address the void in advanced wound care, received a Medicare Part B reimbursement code in 2000, gained inclusion in the diabetic foot ulcer guidelines from the Tucson Expert Consensus Conference in 2004 and recorded worldwide revenue of $1.4 billion from the V.A.C. in 2010.

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

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

Regulatory Matters

FDA Regulation

Each of our products must be cleared or approved 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 product candidate is being reviewed by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case the governmental review requirements could vary in some respects.

FDA Approval or Clearance of Medical Devices

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

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

Each of our product candidates require FDA authorization prior to marketing, by means of either a 510(k) clearance or a PMA approval. We are currently proceeding along the path that dermaPACE is a Class III device requiring a PMA approval. To date, we have corresponded with the FDA pertaining to possible reclassification of PACE technology for certain indications within the Class II designation. The FDA continues to maintain that PACE should remain a Class III technology. Reclassification of the technology is possible but the path through the FDA for such reclassification will be lengthy and involved. In the meantime, we may leverage existing PMA approval for our Ossatron device in order to obtain the same indication (treatment of plantar fasciitis) for our orthoPACE device as a line extension for the technology. This route may not require clinical trials and will be time effective. We may be able to leverage the expected approval for our dermaPACE device in much the same manner for other indications utilizing existing clinical experience.

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

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with Quality System Regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows the panel's recommendation. 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 510(k) submission or PMA application, 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 cleared or approved 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.

The FDA has released new guidelines for approval of a Class II device via the 510(k) process. In the past, the FDA has been criticized for their lack of predictability, reliability, and efficiency of the 510(k) process. Under these new, developing guidelines, the FDA will implement internal programs to address these concerns. The new paradigm is intended to clarify requirements for manufacturers and to streamline the approval process. These changes may also require device manufacturers to provide more clinical data to prove their claims. While we do not anticipate device regulatory pathways via the 510(k) route with our current technology, we intend to remain cognizant of these regulatory changes for future device pathways via this route.

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 this places us in a reduced fee structure. As future revenues exceed a certain annual threshold limit, we may not qualify for the Small Business Manufacturer reduced fee structure 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 are sometimes required to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board (the "IRB") has approved the study.

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

Post-Approval Regulation of Medical Devices

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

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

We continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as do 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

If and when we manufacture medical devices, we will be required to comply with applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practices (the "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 them. 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 body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have an ISO 13485:2003 certification, as well as meet additional requirements of Canadian laws. We currently maintain this certification. We maintain a device license for dermaPACE with Health Canada for the indication of "devices for application of shockwaves (pulsed acoustic waves) on acute and chronic defects of the skin and subcutaneous soft tissue".

The primary regulatory environment in Europe is the European Union, which consists of 25 member states and 42 competent authorities 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 bodies and paths in Asia and Australia are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice ("GMP"), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with GMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking

of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

United States Anti-Kickback and False Claims Laws

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

Third Party Reimbursement

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

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

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

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

The initial phase of establishing a professional billing code for a medical service typically includes applying for a CPT Category III code. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as AMA CPT Editorial Panel review. A new CPT Category III code will be assigned if the AMA CPT Editorial Panel committee deems it meets criteria and is appropriate. In 2011, we received two CPT Category III codes for ESWT in wound healing. Pending approval by the FDA of our PMA application, our dermaPACE would be the first and only ESWT device in the United States capable of utilizing these codes.

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, among other criteria, is based on widespread usage and established clinical efficacy of the medical service.

There are also billing codes that facilities, not 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 based on internal available information. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment. Information on the clinical similarities of ESWT services within the OPPS as well as costs will be provided to the Centers for Medicare & Medicaid Services.

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

Environmental and Occupational Safety and Health Regulations

Our operations are subject to extensive Federal, state, provincial and municipal environmental statutes, regulations and policies, including those promulgated by the Occupational Safety and Health Administration, the United States Environmental Protection Agency, Environment Canada, Alberta Environment, the Department of Health Services, and the Air Quality Management District, that govern activities and operations that may have adverse environmental effects such as discharges into air and water, as well as handling and disposal practices for solid and hazardous wastes. Some of these statutes and regulations impose strict liability for the costs of cleaning up, and for damages resulting from, sites of spills, disposals, or other releases of contaminants, hazardous substances and other materials and for the investigation and remediation of environmental contamination at properties leased or operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. In addition, we may be subject to claims and lawsuits brought by private parties seeking damages and other remedies with respect to similar matters. We have not to date needed to make material expenditures to comply with current environmental statutes, regulations and policies. However, we cannot predict the impact and costs those possible future statutes, regulations and policies will have on our business.

Milestone and Royalty Payments

Under an agreement with Sci-Do AG, an Austrian company from which we purchased certain patents, we are required to make various milestone and royalty payments based on the occurrence of certain events. Pursuant to the terms of the agreement, we are required to make a royalty payment of $100,000 upon FDA approval of our product for wound care. In addition, we are required to make royalty payments, based on a percentage of operating profit, for sales of FDA-approved wound care products in excess of $500,000 of earnings before interest and taxes. There were no payments under the agreement for the years ended December 31, 2011 and 2010.

Employees

As of March 9, 2012, we had a total of 19 full time employees in the United States. Of these, 8 were engaged in research and development, including 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

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

For the year ended December 31, 2011, we had a net loss of $10,238,797 and used $8,831,699 of cash in operations. As of December 31, 2011, we had an accumulated deficit of $64,508,828 and a total stockholders' deficit of $1,536,477.

As a result of our significant research, clinical development, regulatory compliance and general and administrative expenses, we expect to incur losses for at least the next several years as we continue to incur expenses related to seeking FDA approval for our dermaPACE device and then commercialization in the United States after FDA approval, if obtained. Due to uncertainty about our ability to raise capital to fund our ongoing operations, in their report on our annual financial statements for the year ended December 31, 2011, our independent registered public accounting firm included an explanatory paragraph regarding our ability to continue as a going concern. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenues and we may never achieve or be able to maintain profitability.

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 when necessary, and/or the terms of any financings may not be advantageous to us.

The continuation of our business is dependent upon raising additional financial support. For the years ended December 31, 2011 and 2010, the net cash used by operating activities by the Company was $8,831,699 and $5,867,276, respectively. As of December 31, 2011, we had cash and cash equivalents of $3,909,383. The additional financial support may include: raising additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, an investment by a strategic partner in a specific clinical indication or market opportunity; selling all or a portion of the Company's assets, liquidating assets, or seeking relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. 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.

Current economic conditions could adversely affect our operations.

According to the National Bureau of Economic Research, the United States economy was in a recession from December 2007 through June 2009. This economic downturn was the longest recession since World War II. The related instability of markets has impacted us in the short term by making it difficult to raise the necessary capital to fund our operations.

There is a risk that one or more suppliers, clinical investigators, consultants and other partners may encounter difficulties during these challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

The current economic conditions may also adversely affect our potential customers, including patients, medical professionals and their practices, hospitals and other healthcare providers. These conditions may also impact the overall amount spent on healthcare generally. This could result in a decrease in the demand for our products, longer sales cycles, slower adoption of our new technology and increased price competition.

Our product candidates may not be developed or commercialized successfully.

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

We are subject to the risks that:

- the FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;

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

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

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

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

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

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

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

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

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

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

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

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

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

As a small company with 19 employees, our success depends on the continuing contributions of our management team and qualified personnel. Our success depends in large part on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical, biotechnology and medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

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

The use of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims which could result in financial loss. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts or scope, to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management team and other resources, and adversely impact or eliminate the prospects for commercialization of the product candidate, or sale of the product, which is the subject of any such claim. Although we do not promote any off-label use, off-label uses of products are common and the FDA does not regulate a physician's choice of treatment. Off-label uses of any product for which we obtain approval may subject us to additional liability.

Regulatory Risks

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

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate will be safe and effective in advanced clinical trials involving larger 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. We cannot be sure that the FDA will not select a different center and/or different legal authority for our other product candidates, in which case the path to regulatory approval would be different and could be more lengthy and costly.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers, our contract manufacturers and our contract testing laboratories 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, other numerous and pervasive regulatory requirements apply, both before and after approval or clearance, to us, our products and product candidates, and our suppliers, contract manufacturers and contract laboratories. These include requirements related to the following:

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

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

The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers, contract manufacturers and contract laboratories. 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.

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 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, if any, may be.

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

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

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

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

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

We believe that future reimbursement 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 future approved products currently under development and limit our ability to sell our approved products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our approved products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our approved products would be impaired and our future revenues, if any, would be adversely affected.

Healthcare policy changes, including the recently enacted legislation to reform the United States healthcare system, may have a material adverse effect on us.

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

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, beginning in 2013;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests, with the first of such reports due March 31, 2013 for calendar year 2012;
- 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, beginning on or before January 1, 2013;

- 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.

These provisions could meaningfully change the way healthcare is delivered and financed, and could have a material adverse impact on numerous aspects of our business.

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

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in markets where we do business. We could experience an adverse impact on our operating results due to increased pricing pressure in the United States and in other markets. Governments, hospitals and other third party payors could reduce the amount of approved reimbursement for our products or deny coverage altogether. Reductions in reimbursement levels or coverage or other cost-containment measures could adversely affect our future operating results.

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

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

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

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.

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

Risks Related to Intellectual Property

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

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

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

The degree of intellectual property protection for our technology is uncertain, and only limited intellectual property protection may be available for our product candidates, which may prevent us from gaining or keeping any competitive advantage against our competitors. Although we believe the patents that we own or license, and the patent applications that we own or license, generally provide us a competitive advantage, the patent positions of biotechnology, biopharmaceutical and medical device companies are generally highly uncertain, involve complex legal and factual questions and have been the subject of much litigation. Neither the United States Patent & Trademark Office nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Further, a court or other government agency

could interpret our patents in a way such that the patents do not adequately cover our current or future product candidates. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

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

In particular, we cannot assure you that:

- we or the owners or other inventors of the patents that we own or that have been licensed to us, or that may be issued or licensed to us in the future, were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our patent applications will result in issued patents;
- the patents and the patent applications that we own or that have been licensed to us, or that may be issued or licensed to us in the future, will provide a basis for commercially viable products or will provide us with any competitive advantages, or will not be challenged by third parties;
- the patents and the patent applications that have been licensed to us are valid and enforceable;
- we will develop additional proprietary technologies that are patentable;
- we will be successful in enforcing the patents that we own or license and any patents that may be issued or licensed to us in the future against third parties;
- the patents of third parties will not have an adverse effect on our ability to do business; or
- our trade secrets and proprietary rights will remain confidential.

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

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

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

we may file in the future, or may result in patents that issue alongside patents issued to us or our licensors or that may be issued or licensed to us in the future, leading to uncertainty over the scope of the patents owned by or licensed to us or that may in the future be owned by us or our freedom to practice the claimed inventions.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

- unforeseen developments during our pre-clinical activities and clinical trials;
- delays in timing of receipt of required regulatory approvals;
- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of any approved product;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using any of our approved products;
- inability to train a sufficient number of physicians to create a demand for any of our approved products;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- unforeseen problems with our third party manufacturers, service providers or specialty suppliers of certain raw materials;
- unanticipated difficulties in operating in international markets;
- unanticipated financial resources needed to respond to technological changes and increased competition;
- unforeseen problems in attracting and retaining qualified personnel to market our approved products;
- enactment of new legislation or administrative regulations;
- the application to our business of new court decisions and regulatory interpretations;
- claims that might be brought in excess of our insurance coverage;
- the failure to comply with regulatory guidelines; and
- the uncertainty in industry demand and patient wellness behavior as businesses and individuals suffer from the current economic downturn.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements. If adequate financing is not available, we may be required to delay, scale back or eliminate our operations. Consequently, our long-term viability would be threatened.

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

In the past, we have relied on Prides Capital Partners, LLC (“Prides Capital”) and NightWatch Capital LLC (“NightWatch Capital”) for the ongoing financial support necessary to operate our business. Neither Prides Capital nor NightWatch Capital currently provides us with financing or financial support, nor do they currently intend to provide us with any additional financing or financial support in the future. To the extent we must obtain financing to support our cash needs, we will be entirely reliant on third parties. We do not have any lines of credit or other financing arrangements in place with banks or other financial institutions. We will require additional financing in the future, and additional financing may not be available at times, in amounts or on terms acceptable to us, or at all, which would have a material adverse effect on our business.

Prides Capital and NightWatch Capital control and may continue to control us and may have conflicts of interest with us or you in the future.

As of March 9, 2012, Prides Capital owned 43.4% of our outstanding common stock and NightWatch Capital owned 9.1% of our outstanding common stock. In addition, Kevin A. Richardson, II, who is managing partner of Prides Capital, owns 6.9% of our outstanding common stock. Mr. Richardson was appointed by Prides Capital and John F. Nemelka was appointed by NightWatch Capital to serve on our board of directors. For as long as Prides Capital and NightWatch Capital own a majority of our shares of common stock, they will be able to control the election of all of the members of our board of directors and control the vote of shareholders on other matters. For as long as they own a significant percentage of our outstanding stock, even if less than a majority, Prides Capital and NightWatch Capital will be able to control and exercise significant influence over our business affairs, including the general strategic direction of our business, the incurrence of indebtedness by us, the issuance of any additional equity securities, the repurchase of equity securities and the payment of dividends, and will have the power to determine or significantly influence the outcome of matters submitted to a vote of our shareholders, including mergers, consolidations, sales or dispositions of assets, reductions in share capital, other business combinations and amendments to our articles of incorporation. Prides Capital and NightWatch Capital may take actions with which you or we do not agree, including actions that delay, defer or prevent a change in control of our Company or that could adversely affect the market price of our common stock. In addition, they may take other actions that might be favorable to them, but not favorable to us or our other shareholders. Also, if either Prides Capital or NightWatch Capital sells all or a portion of its interest in us, it may cause the value of your investment to decrease.

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:

- changes in the timing of regulatory approvals for our product candidates or failure to obtain such regulatory approvals;
- changes in our industry;
- our ability to obtain additional financing and, if available, the terms and conditions of the financing;
- additions or departures of key personnel;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- period-to-period fluctuations in our operating results;
- new regulatory requirements and changes in the existing regulatory environment; and
- general economic conditions and other external factors.

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

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

To date, there has been a limited trading market for our common stock and we cannot predict how liquid the market for our common stock might become. Our common stock is quoted on the Over-the-Counter Bulletin Board (the "OTCBB"), which is an inter-dealer, over-the-counter market that provides significantly less liquidity than the New York Stock Exchange or the NASDAQ Stock Market. The quotation of our common stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market currently 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.

SEC regulations 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.

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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our operations are headquartered in a leased facility in Alpharetta, Georgia, consisting of 15,025 square feet of space under a sublease which expires on October 31, 2012.

Our production and research and development office is in a leased facility in Alpharetta, Georgia, consisting of 5,168 square feet of space under a lease which expires on October 31, 2012.

We are working on extending or renewing leases within our current facilities or relocating to other local facilities when the leases expire. We do not foresee there being any interruption in our business if we were to relocate in the local area.

Item 3. LEGAL PROCEEDINGS

Other than the legal proceeding described below and those relating to our intellectual property, there are no material pending legal proceedings to which we are a party or of which any of our properties are subject; nor are there material proceedings known to us to be contemplated by any governmental authority. We have one pending legal proceeding relating to our patents. For information regarding this legal proceeding, please see "Business - Intellectual Property – Patents" above.

HealthTronics, Inc., along with the Company, are defendants in an alleged breach of contract lawsuit dated April 21, 2006 brought in the Miami-Dade County Circuit Court, Florida by a former limited partner of a former limited partnership of the Company, Bone & Joint Treatment Centers of America. Bone & Joint Treatment Centers of America, the plaintiff, is seeking greater than $3 million. The lawsuit went to trial in 2011 and the Company received a summary judgment in its favor in December 2011. On January 5, 2012, the plaintiff filed an appeal of the summary judgment. HealthTronics, Inc. has been responsible for the defense of the lawsuit on behalf of the Company and believes the case is unfounded and is contesting the claims vigorously.

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 OTCBB under the symbol "SNWV."

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

	Price Range	
	High	Low
2011		
First Quarter	$5.72	$3.75
Second Quarter	$5.72	$3.00
Third Quarter	$3.75	$2.70
Fourth Quarter	$2.70	$0.15

	Price Range	
	High	Low
2010		
First Quarter	$4.30	$4.05
Second Quarter	$4.45	$4.10
Third Quarter	$4.10	$2.25
Fourth Quarter	$4.80	$2.15

Holders of the Common Stock

As of March 9, 2012, there were 68 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	-	-	-
Equity compensation plans not approved by security holders	4,365,546	$2.82	2,322,899
Total	4,365,546	$2.82	2,322,899

Stock Incentive Plans

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

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Amended Plan"). The Amended Plan permits grants of awards to selected employees and directors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include nonstatutory options as well as qualified incentive stock options. The Amended Plan is currently administered by the board of directors of the Company. The Amended 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 Amended Plan are nonstatutory options which vest over a period of up to four 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 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are an emerging global regenerative medicine company focused on the development and commercialization of noninvasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. Our portfolio of 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/spine, plastic/cosmetic and cardiac conditions.

We believe we have demonstrated that our technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved Ossatron device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our Ossatron, Evotron, and orthoPACE devices in Europe. Our lead product candidate for the global wound care market, dermaPACE, has received the European Community CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. We currently do not have any commercial products in the United States. Revenues are from sales of CE Marked devices and accessories in Europe.

We are now entirely focused on developing our PACE technology to stimulate healing in:

- wound conditions, including diabetic foot ulcers, venous ulcers, pressure sores, burns and other skin eruption conditions;
- orthopedic/spine applications, such as speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, eliminating chronic pain in joints from trauma or arthritis, and other potential sports injury applications;
- plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and
- cardiac applications for removing plaque due to atherosclerosis and improving heart muscle performance.

Recent Developments

Our lead device product for the global wound care market, dermaPACE, has received the European Community CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue, and has completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to Sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and Sham-control at 12 weeks in the ITT population was not statistically significant at the 95% confidence level used throughout the study ($p=0.363$). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) Sham-control subjects.
- In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of Sham-control subjects ($p=0.047$); in the EE population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of Sham-control subjects ($p=0.018$); at 24 weeks dermaPACE achieved 40% complete wound closure in the ITT population ($p=0.054$) and 41% complete wound closure in the EE population ($p=0.022$).
- Subjects treated with dermaPACE achieved a significant increase in the rate of complete wound closure or ≥90% wound area reduction by or at 12 weeks ($p<0.05$).
- Within 6 weeks following the initial dermaPACE procedure, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive Sham-control ($p<0.05$).
- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20% in the Sham-control group.

- Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the Sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

We filed with the FDA the third and final module of the dermaPACE PMA application in June 2011. In December 2011, we received a major deficiency letter from the FDA regarding the FDA's review of the dermaPACE PMA. The FDA issues a major deficiency letter to the applicant when the PMA lacks significant information necessary for FDA to complete its review or to determine whether there is reasonable assurance that the device is safe and effective for its intended use. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's previously disclosed failure to meet the study's primary endpoint of 100% wound closure compared with Sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency is for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We have evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we now expect to conduct additional clinical work to provide support for the FDA to approve the dermaPACE PMA. We have finalized our clinical study plan and submitted our IDE supplement for conditional approval to the FDA in March 2012. At a minimum, we expect the additional clinical work to take up to 24 months before completion and submission to the FDA. Therefore, in 2012 we have taken meaningful cost cutting measures to reduce our monthly cash needs. In addition, we have formed a special committee of our board of directors who have retained Canaccord Genuity Inc., a leading investment bank, to explore capital fund raising and/or strategic options to fund us while we complete this additional clinical work.

We have received two Category III CPT codes for ESWT in wound healing. CPT Category III codes are a set of tracking codes established by the AMA that permit data collection for emerging technology, services and procedures. Pending approval by the FDA of our PMA application, the dermaPACE would be the first and only ESWT device in the United States capable of utilizing these codes.

There are also billing codes that facilities, not 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 based on internal available information. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment. Information on the clinical similarities of ESWT services within the OPPS as well as costs will be provided to the Centers for Medicare & Medicaid Services.

We launched in Europe the orthoPACE device intended for use in orthopedic, trauma and sports medicine indications following CE Mark approval in June 2010. The device features a new, 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 will initially be 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.

Financial Overview

Since our inception in 2005, we have funded our operations from the sale of capital stock, 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. At December 31, 2011, the balance of cash and cash equivalents totaled $3,909,383.

We will require additional capital in 2012 to continue to implement our business strategies. There can be no assurance that we will be successful in raising such capital. See "Liquidity and Capital Resources."

We continue to incur research and development expenses for clinical trials and the development of products for additional indications. We expect to continue to incur significant research and development expenses as a result of new and ongoing clinical and pre-clinical studies in the United States and in Europe, as well as expenses associated with regulatory filings, which may include expenses related to responding to regulatory comments and/or directives following review of our filings/applications. In addition, we anticipate that our general and administrative expenses will increase in the future when we expand our operations, facilities and other administrative activities related to our efforts to bring our product candidates to commercialization.

Since our inception, we have incurred losses from operations each year. As of December 31, 2011, we had an accumulated deficit of $64,508,828. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next several years as we continue to fund our research and development activities, clinical trials and the FDA approval process and as we prepare for a future sales network to represent our products. We incurred a net loss of $10,238,797 and $14,922,441 during the years ended December 31, 2011 and 2010, respectively. These operating losses create an uncertainty about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing will provide the necessary funding for us to continue as a going concern.

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

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of successful marketing, sales and distribution;
- the cost and timing associated with establishing reimbursement for our products;
- the timing and results of our pre-clinical research programs;
- 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 of allowances for deferred taxes, the estimated fair value of stock-based compensation, the estimated fair value of intangible assets, the estimated fair value assigned to the capital stock units exchanged for promissory notes and the estimated fair value assigned to the common stock and warrants exchanged for the notes payable, related parties. 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, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

service is performed.

Research and Development Costs

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

Inventory Valuation

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

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

Stock-based Compensation

On November 1, 2010, the board of directors of the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the “Amended Plan”). The Amended Plan provides that stock options, and other equity interests or equity-based incentives, may be granted to key personnel and directors at the fair value of the common stock at the time the option is granted, which is approved by the Company’s board of directors. The maximum term of any option granted pursuant to the Amended Plan is ten years from the date of grant.

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

Income Taxes

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, Income Taxes (formerly SFAS No. 109, Accounting for Income Taxes). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets related to future years, including loss carryforwards, if there is not sufficient evidence to indicate that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in future years.

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

Results of Operations for the Years ended December 31, 2011 and 2010

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2011 were $802,572, compared to $728,446 for the same period in 2010, an increase of $74,126, or 10%. Revenues resulted primarily from sales in Europe of our dermaPACE and orthoPACE devices and related applicators. The increase in revenues for 2011 is due to increased sales of orthoPACE devices and applicators introduced in Europe in mid year 2010 for orthopedic, trauma and sports medicine indications.

Cost of revenues for the year ended December 31, 2011 was $261,890, compared to $250,326 for the same period in 2010. Gross profit as a percentage of revenues was 67% for the year ended December 31, 2011 and 66% for the same period in 2010.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2011 were $2,731,059, compared to $3,879,146 for the same period in 2010, a decrease of $1,148,087, or 30%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical related consultants, contract manufacturer development costs and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs. Research and development expenses decreased in 2011 due to lower expenses related to clinical site payments, clinical monitoring and clinical database charges for the clinical trial of dermaPACE for treating diabetic foot ulcers in the United States as enrollment and patient follow-up ended during 2010. The costs for 2011 transitioned to consulting expenses for clinical results analysis and preparation of the dermaPACE device Premarket Approval application with the FDA.

We expect to continue to incur significant research and development expenses as a result of continued work on our clinical trial of dermaPACE for diabetic foot ulcers in the United States and other new product candidates, as well as continuing expenses associated with pre-clinical studies and regulatory filings in addition to next generation technology development.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2011 were $6,292,950, compared to $7,100,621 for the same period in 2010, a decrease of $807,671, or 11%. General and administrative expenses included non-cash stock-based compensation of $1,118,813 and $3,037,634 for the years ended December 31, 2011 and 2010, respectively. The decrease in non-cash stock-based compensation of $1,918,821 for the year ended December 31, 2011, as compared to the same period in 2010, was primarily due to the restricted stock granted in 2009 becoming fully vested and expensed in 2010.

Excluding non-cash stock-based compensation, general and administrative expenses were $5,174,137 for the year ended December 31, 2011, as compared to $4,062,987 for the same period in 2010, an increase of $1,111,150, or 27%. The increase in general and administrative expenses is primarily due to increased sales and marketing expenses for medical society tradeshows, increased investor relations expenses and increased legal costs as a result of patent preparation, filing and defense activities.

We expect that general and administrative expenses will increase in the future when we expand our operations and other administrative activities related to our efforts to bring our products to commercialization.

Depreciation, Amortization and Write Down of Assets Held for Sale

Depreciation for the year ended December 31, 2011 was $19,034, compared to $829,576 for the same period in 2010, a decrease of $810,542, or 98%. As of December 31, 2010, management determined that there was no viable market for selling our used Ossatron mobile service devices due to the age of the devices and changes in international electrical standards with which the devices are no longer compliant. Management currently has no plans to utilize these devices in the United States. The combination of these factors contributed to management's decision to write down these assets. Therefore, as of December 31, 2010, we recorded additional depreciation expense of $201,153 to fully depreciate the used Ossatron devices and recorded a write down of assets held for sale of $169,581 to fully reserve for the related parts inventory for these devices.

Amortization for the year ended December 31, 2011 was $306,756, compared to $306,757 for the same period in 2010.

Other Income (Expense)

In June 2009, we sold our veterinary division to Pulse Veterinary Technologies, LLC ("Pulse Vet"). Under terms of the asset purchase agreement, we continued to provide transitional production services at the direction of Pulse Vet for a fee until these transitional production services were transitioned to Pulse Vet. Pulse Vet took over production services effective November 1, 2011. The income for these transitional services was $375,000 and $360,125 for the years ended December 31, 2011 and 2010, respectively, an increase of $14,875 or 4%. The increase was due to the contractual increase in fees for the monthly services effective January 1, 2011.

On April 4, 2011, we amended the terms of outstanding notes with Prides Capital Fund I, LP and NightWatch Capital Partners II, LP such that the unpaid principal and interest balance on the notes totaling $4,413,908 was cancelled in consideration of the issuance of 1,358,126 shares of common stock. In addition, in connection with the transaction, we issued to the noteholders warrants to purchase an aggregate of 679,064 shares of common stock at an exercise price of $4.00 per share. We recorded a loss from extinguishment of debt of $1,318,781, which was the difference between the estimated fair value of the common stock and warrants on the date of exchange and the fair value of the notes (assuming the conversion feature was exercised by the noteholders).

During the year ended December 31, 2010, we issued ten promissory notes totaling $2,450,000. On October 12, 2010, in conjunction with an offering of securities, we amended the terms of the ten outstanding promissory notes such that the unpaid principal and interest on each note was exchanged into units consisting of a share of common stock, a Class D warrant, and an option which, as amended, expired on January 31, 2011, to purchase another share of common stock and a Class D warrant. We recorded a loss from extinguishment of debt of $2,693,896 which was the difference between the estimated fair value of the units on the date of exchange of $5,211,556 as compared to the carrying value of the promissory notes of $2,517,660.

Interest expense, net, for the year ended December 31, 2011 was $472,155, compared to $961,585 for the same period in 2010, a decrease of $489,430, or 51%. The decrease was due to no interest expense after April 4, 2011 on certain notes payable to related parties as a result of the note exchange for common stock and warrants on that date as discussed above.

Provision for Income Taxes

In November 2010, we were awarded a cash grant totaling $244,479 under the United States government's Qualifying Therapeutic Discovery Project ("QTDP") program. The QTDP program was created by the United States Congress as part of the Patient Protection and Affordable Care Act of 2010, and provided a tax credit or grant equal to eligible costs and expenses for tax years 2009 and 2010. The QTDP program was aimed at creating and sustaining high-quality, high-paying jobs in the United States, while advancing the nation's competitiveness in life, biological and medical sciences. We submitted an application and received the award based on our dermaPACE IDE study for diabetic foot ulcers.

At December 31, 2011, we had federal net operating loss carryforwards of $48,915,087 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a "more than 50% change in ownership" which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we

may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the year ended December 31, 2011 was $10,238,797, or ($0.52) per basic and diluted share, compared to a net loss of $14,922,441, or ($1.15) per basic and diluted share, for the same period in 2010. We anticipate that our operating losses will continue over the next several years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products.

Liquidity and Capital Resources

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources to continue our research and development efforts, including clinical trials. Because of the significant time it will take for our products to complete the clinical trial process, and for us to obtain approval from regulatory authorities and successfully commercialize our products, we will require substantial additional capital resources. We incurred a net loss of $10,238,797 and $14,922,441 for the years ended December 31, 2011 and 2010, respectively. These operating losses create uncertainty about our ability to continue as a going concern. For the years ended December 31, 2011 and 2010, the net cash used by operating activities by the Company was $8,831,699 and $5,867,276, respectively. As of December 31, 2011, we had cash and cash equivalents of $3,909,383. We may raise additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, or an investment by a strategic partner in a specific clinical indication or market opportunity, or we may sell all or a portion of the Company's assets, liquidate assets, or seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

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

On April 8, 2011, we completed a private placement to 28 institutional and individual accredited investors of 2,804,593 shares of common stock at a purchase price of $3.25 per share, for gross proceeds of $9,114,927. The net proceeds received by us were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of common stock at an exercise price of $4.00 per share. In addition, the placement agent for the private placement was issued five-year warrants to purchase 93,080 shares of common stock at an exercise price of $4.00 per share. The warrants vested upon issuance and expire after five years.

On April 4, 2011, Prides Capital Fund I, LP and NightWatch Capital Partners II, LP, the holders of the amended senior notes, exchanged the unpaid principal and interest balance of the notes which totaled $4,413,908 in consideration for the issuance of 1,358,126 shares of common stock. In connection with this transaction, we issued to the noteholders an aggregate total of 679,064 warrants to purchase shares of common stock at an exercise price of $4.00 per share. Each warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expire after five years.

Between September 30, 2010, and December 7, 2010, we issued 925,000 units to certain accredited investors for an aggregate total purchase price of $1,850,000. Each unit was sold to the new investors at a purchase price of $2.00 per unit. As a result of the offerings, we sold 925,000 units which consisted of 925,000 shares of common stock, 925,000 Class D warrants and 925,000 options, which, as amended, expired on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit. As of December 31, 2010, the option holders exercised 101,163 options for total gross proceeds of $202,326 to us. In connection with the exercise of the options, we issued 101,163 shares of common stock and 101,163 Class D warrants. Between January 1 and January 31, 2011, the option holders exercised 1,950,167 options for total gross proceeds of $3,900,334 to us. In connection with the exercise of options, we issued 1,950,167 shares of common stock and 1,950,167 Class D warrants. The 132,500 options that remained unexercised at January 31, 2011 expired by their terms.

During 2010, we issued ten promissory notes totaling $2,450,000. On October 12, 2010, the unpaid principal and interest on the notes totaled $2,517,660, and this sum was exchanged into a total of 1,258,830 units which consisted of 1,258,830 shares of common stock, 1,258,830 Class D warrants and 1,258,830 options, which, as amended, expired on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit.

For the year ended December 31, 2011, net cash used by operating activities was $8,831,699, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. In addition, the net cash used by operating activities during 2011 included payments to reduce current payables, accrued employee compensation and accrued expenses which totaled $1,607,856. Net cash used by investing activities for the year ended December 31, 2011 was $42,302, which consisted of the purchase of fixed assets used for research and development and computer equipment. Net cash provided by financing activities for the year ended December 31, 2011 was $12,366,363, which primarily consisted of the net proceeds from the private placement of $8,467,121 and the exercise of unit options of $3,900,334. Cash and cash equivalents increased by $3,491,926 for the year ended December 31, 2011.

For the year ended December 31, 2010, net cash used by operating activities was $5,867,276, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by financing activities for the year ended December 31, 2010 was $4,502,326, which consisted of the proceeds from the issuance of promissory notes totaling $2,450,000 and from the sale of capital stock units totaling $2,052,326. Cash and cash equivalents decreased by $1,368,912 for the year ended December 31, 2010.

Segment Information

We have determined that we are principally engaged in one operating segment. Our product candidates are primarily used for the repair and regeneration of tissue, musculoskeletal and vascular structures in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions.

Other Comprehensive Income (Loss)

FASB ASC 220, Comprehensive Income (formerly SFAS No. 130, Reporting Comprehensive Income), establishes standards for reporting and display of comprehensive income (loss) and its components in the consolidated financial statements. Our other comprehensive income (loss) as defined by ASC 220 is the total of net income (loss) and all other changes in equity resulting from non-owner sources, including unrealized gains (losses) on foreign currency translation adjustments.

Contractual Obligations

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

In October 2006, we entered into a sublease agreement for the corporate office in Alpharetta, Georgia for 15,025 square feet of space. Under the terms of the sublease, we pay monthly rent of $18,468, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the sublease expired September 30, 2009, and we exercised the option to extend the term to October 31, 2012.

In April 2007, we entered into a lease agreement for the production and research and development office for 5,168 square feet of space. Under the terms of the lease, we pay monthly rent of $9,785, as adjusted on an annual basis for

additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the lease expired on July 31, 2010, and we extended the lease until October 31, 2012.

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

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, Inc., we issued two notes to HealthTronics, Inc. for $2,000,000 each. The notes bear interest at 6% annually. Quarterly interest through June 30, 2010 was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal is due August 1, 2015. Accrued interest on the notes not payable until August 2015 totaled $1,372,743 at December 31, 2011 and 2010.

Recently Issued Accounting Standards

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

Off-Balance Sheet Arrangements

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

Effects of Inflation

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

On July 18, 2011, we dismissed HLB Gross Collins, P.C. (“HLB Gross Collins”) as our principal independent registered public accounting firm. The decision to dismiss HLB Gross Collins was approved by our board of directors.

In the fiscal years ended December 31, 2010 and 2009, HLB Gross Collins’s report on our consolidated financial statements did not contain an adverse opinion or disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope or accounting principles, except that each of HLB Gross Collins’ reports on our consolidated financial statements contained a going concern explanatory paragraph, expressing substantial doubt about our ability to continue as a going concern due to our substantial operating losses, working capital deficiencies and dependence on future capital contributions or financing to fund ongoing operations.

In the fiscal years ended December 31, 2010 and 2009, and through July 18, 2011, there were no disagreements, as that term is defined in Item 304(a)(1)(iv) and the related instructions of Regulation S-K, promulgated by the SEC pursuant to the Exchange Act, with HLB Gross Collins on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of HLB Gross Collins, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its report on the Company’s financial statements.

In the fiscal years ended December 31, 2010 and 2009, and through July 18, 2011, there were no "reportable events," as that term is defined in Item 304(a)(1)(v) of Regulation S-K, that were reported by HLB Gross Collins to us.

On July 18, 2011, we engaged BDO USA, LLP ("BDO") as our principal independent registered public accounting firm to audit our consolidated financial statements for the fiscal year ending December 31, 2011. The decision to engage BDO was approved by our board of directors.

During the fiscal years ended December 31, 2010 and 2009, and through July 18, 2011, we, nor anyone acting on our behalf, consulted with BDO regarding (i) either: the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our consolidated financial statements, and no written report or oral advice was provided to us that BDO concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) and the related instructions of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2011. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2011.

The Company had previously reported, as of December 31, 2010, a material weakness in the Company's internal control over financial reporting attributable to the lack of internal expertise and resources to analyze and properly apply United States generally accepted accounting principles to complex and non-routine transactions related to the appropriate treatments of complex financial instruments, derivatives and stock-based compensation. 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. Management believes the material weakness was due to the complex and non-routine nature of the Company's complex financial instruments, derivatives and stock-based compensation.

Management's Annual Report on Internal Control over Financial Reporting

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

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

Management, with the participation of the Chief Executive Officer (principal executive officer) and the Chief Financial Officer (principal financial officer), evaluated the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework. As a result of such assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2011.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting, except we redesigned the procedures to enhance the identification, capture, review, approval and recording of contractual terms, including equity arrangements, and added a control for management to engage, as necessary, an outside consultant to assist in the application of United States generally accepted accounting principles to complex transactions.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

MANAGEMENT

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

Name	Age	Position Held
Christopher M. Cashman	44	President, Chief Executive Officer and Director Officer
Barry J. Jenkins	49	Chief Financial Officer
Barbara M. Henagan	52	Director
John F. Nemelka	46	Director
Kevin A. Richardson, II	43	Director
Thomas H. Robinson	53	Director
Ronald M. Sparks, Jr	56	Director

Christopher M. Cashman joined the Company as Chief Executive Officer and President in September of 2009 and as a director in October of 2009, and joined SANUWAVE, Inc. as President, Chief Executive Officer and a director in December of 2005. Mr. Cashman brings to our board of directors, among other skills and qualifications, a unique understanding of our strategies and operations through his years of experience with various public and private healthcare companies. Immediately prior to joining SANUWAVE, Inc., he served as President of Therapeutic Surfaces for Kinetic Concepts, Inc., a global leader in advanced wound care, from October of 2005 to December of 2005. In November of 2001, Mr. Cashman conducted a management buyout from Genzyme Corporation of Snowden Pencer, Inc., a minimally invasive surgical device manufacturer, and assumed the role of Chief Executive Officer and President until Snowden Pencer, Inc. was sold to Cardinal Health, Inc. in March 2004. Mr. Cashman also previously served as a business unit head with Genzyme Biosurgery and held several senior sales and marketing positions with Genzyme Surgical Products and Deknatel Snowden Pencer. Mr. Cashman graduated from the United States Naval Academy in 1989 with a B.S. in Economics and served on a fast attack submarine as Supply Officer. He received his M.B.A. in 2001 from the Kellogg Graduate School of Management at Northwestern University.

Barry J. Jenkins joined the Company as Chief Financial Officer in September of 2009 and joined SANUWAVE, Inc. as Chief Financial Officer in April of 2006. Prior to joining SANUWAVE, Inc., he served as Chief Financial Officer for the Benefit Services Division of Automatic Data Processing, Inc. from March of 2005 to April of 2006. Previously, he was the Chief Financial Officer of Snowden Pencer, Inc. from January of 2002 to November of 2004. Mr. Jenkins is a certified public accountant with 28 years of financial management experience and a cum laude graduate of Virginia Tech.

Barbara M. Henagan joined the Company as a member of the board of directors in September of 2011. Ms. Henagan brings to the board of directors more than 30 years of direct private equity investing experience. She is a founding member of Linx Partners, a private equity investment firm that partners with family owners, entrepreneurs and management to acquire and grow middle-market industrial companies which was founded in 1999. Previously, she was Senior Managing Director of Bradford Ventures, Ltd. Ms. Henagan is Chairman of the Board of Metaltech Service Center, Inc. and is a member of the Board of Trustees of the Atlanta Speech School and the Atlanta Botanical Garden, where she previously served as Chairman. She is on the Board of Councilors of The Carter Center and is a

member of the Goizueta Business School Advisory Board of Emory University. Ms. Henagan holds an MBA from Columbia University and a BA from Princeton University.

John F. Nemelka joined the Company as a member of the board of directors in October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Nemelka brings to our board of directors a diverse background with both financial and operations experience. Since 2001, Mr. Nemelka has served as a managing principal of NightWatch Capital Advisors, LLC, an investment management firm. Mr. Nemelka is also interim Chief Executive Officer and a member of the board of directors of SWK Holdings Corporation, a publicly traded holding company, formerly KANA Software, Inc., a provider of customer service software solutions. Mr. Nemelka is also a member of the board of directors of LiqTech International, Inc., a publicly traded cleantech company.

Kevin A. Richardson, II joined the Company as chairman of the board of directors in October of 2009 and joined SANUWAVE, Inc. as chairman of the board of directors in August of 2005. Mr. Richardson brings to our board of directors a broad array of financial knowledge for healthcare and other industries. Since 2004, Mr. Richardson has served as managing partner of Prides Capital LLC, an investment management firm. Mr. Richardson is also a member of the board of directors of eDiets.com, Inc., a publicly traded weight loss solutions company, and Pegasus Solutions, Inc., a travel technology company.

Thomas H. Robinson joined the Company as a member of the board of directors in October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Robinson brings to our board of directors experience based on his work with medical device companies both in providing executive search services to them as well as serving in leadership and director positions. Mr. Robinson is a founding partner of RobinsonButler, an executive search firm established in 2011. From 2010 to 2011, Mr. Robinson served as a partner with Russell Reynolds Associates, a global executive search firm, in their global Medical Technology Practice leading senior executive searches. From 1998 to 2010, Mr. Robinson served as managing partner of Spencer Stuart, Inc.'s North American medical technology practice. From 1993 to 1997, Mr. Robinson served as President of the emerging markets business at Boston Scientific Corporation, a global medical devices manufacturer. From 1991 to 1993, Mr. Robinson served as President and Chief Operating Officer of Brunswick Biomedical, a cardiology medical device company. Mr. Robinson is also a member of the board of directors and is chairman of the compensation committee of Cynosure, Inc., a publicly traded aesthetic medical laser company.

Ronald M. Sparks, Jr. joined the Company as a member of the board of directors in September of 2011. Mr. Sparks brings to our board of directors an extensive experience in the medical device industry, specifically in wound care and orthopedics. Since February 2008, Mr. Sparks has served as the Chief Executive Officer and Chairman of Navilyst Medical, Inc., a best-in-class image-guided medical solutions company. He also serves as an Industry Executive at Avista Capital Holdings, L.P., a leading private equity firm, since 2007. Previously, Mr. Sparks served as President, Chief Executive Officer and Executive Director for Accellent Inc., the largest provider of integrated contract manufacturing and design services to the medical device industry. In November 2005, Mr. Sparks led the sale of Accellent to the private equity firm Kohlberg Kravis Roberts & Co. in a transaction valued at approximately $1.3 billion. Prior to Accellent, Mr. Sparks had a 20-year career at Smith & Nephew, plc, where he was a Member of the Group Executive Committee and served as President of the Endoscopy Division from 1998 to 2003. Mr. Sparks served as the President of the Wound Management Division from 1995 to 1998. While at Smith & Nephew, he was integrally involved in the successful launch of Dermagraft®, a cell based therapy used to treat diabetic foot ulcers. He has served as Trustee of the Arthroscopy Association of North America Education Foundation since 2006, is an Honorary Fellow of the American Sports Medicine Institute and is an honorary member of the International Society of Arthroscopy Knee Surgery and Orthopaedic Sports Medicine. Mr. Sparks graduated from the University of Massachusetts with a BA in Finance and Accounting, and completed the INSEAD Advanced Management Program in Fontainebleau, France.

CORPORATE GOVERNANCE

The Company adopted a formal Corporate Governance policy on January 17, 2012 which included establishing formal board committees and a code of conduct for the board of directors and the Company.

Board and Committee Meetings

The Company's current board of directors consists of six members, three of whom have been determined by the board to be "independent" as defined under the rules of the NASDAQ stock market. The independent directors are Barbara M. Henagan, Thomas H. Robinson and Ronald M. Sparks, Jr.

Board’s Leadership Structure

The Company’s board of directors elects the Company's chief executive officer and its chairman, and each of these positions may be held by the same person or may be held by two persons. The Company’s board of directors has determined that it is currently in the best interest of the Company and its shareholders to separate the roles of chairman of the board and chief executive officer. The chairman’s primary responsibilities are to manage the board and serve as the primary liaison between the board of directors and the chief executive officer, while the primary responsibility of the chief executive officer is to manage the day-to-day affairs of the Company, taking into account the policies and directions of the board of directors. Such an arrangement promotes more open and robust communication among the board, and provides an efficient decision making process with proper independent oversight.

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

As of January 17, 2012, the Company’s board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, which will assist the Company’s board of directors in discharging its responsibilities.

Board’s Role in Risk Oversight

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

Audit Committee

The current members of the Company’s audit committee are Barbara M. Henagan, John F. Nemelka and Ronald M. Sparks, Jr. Ms. Henagan, who chairs the committee, has been determined by the board of directors to be an audit committee financial expert as defined pursuant to the rules of the SEC. The board of directors has determined that Ms. Henagan and Mr. Sparks are independent under the applicable marketplace rules of the NASDAQ stock market and Rule 10A-3 under the Exchange Act. Pursuant to the Company’s Audit Committee Charter, the audit committee is required to consist of at least two independent directors. If the audit committee is comprised of at least three members, then, in certain instances one member may be not independent. Ms. Henagan and Mr. Sparks are independent, but Mr. Nemelka is not considered independent due to his affiliation with a company that holds securities of the Company. The board of directors has determined that, although Mr. Nemelka is not independent within the definition of the NASDAQ marketplace rules, exceptional and limited circumstances exist such that the best interests of the Company and its shareholders are served by the membership of Mr. Nemelka on the audit committee. As one of the founding directors of the Company, Mr. Nemelka has acquired a deep understanding of the Company’s operations and audit and financial reporting functions. As an executive in the financial services industry, he has achieved a high degree of financial sophistication, and these qualities make him a uniquely valuable member of the audit committee. The board of directors has reviewed Mr. Nemelka’s business relationship with the Company that disqualifies him as independent under the definition of the NASDAQ marketplace rules and has concluded that this

relationship will not impair his ability to fulfill his responsibilities as a member of the audit committee.

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

Compensation Committee

The current members of the Company's compensation committee are Barbara M. Henagan, Kevin A. Richardson, II, Thomas H. Robinson, and Ronald M. Sparks, Jr. Mr. Robinson is the chairman of the committee. The primary purpose of the compensation committee is to discharge the responsibilities of the board of directors relating to compensation of the Company's executive officers. Pursuant to the Company's Compensation Committee Charter, the compensation committee is required to consist of at least two independent directors. If the compensation committee is comprised of at least three members, then, in certain instances one member may be not independent. The board of directors has determined that Ms. Henagan, Mr. Robinson and Mr. Sparks are independent under the applicable NASDAQ marketplace rules and Rule 10A-3 under the Exchange Act. Mr. Richardson is not considered independent due to his holding of securities of the Company and affiliation with a company that holds securities of the Company. The board of directors has determined that, although Mr. Richardson is not independent within the definition of the NASDAQ marketplace rules, exceptional and limited circumstances exist such that the best interests of the Company and its shareholders are served by the membership of Mr. Richardson on the compensation committee. As the founding chairman of the board of directors of the Company, Mr. Richardson has acquired a deep understanding of the Company's operations. As an executive in the financial services industry, he has achieved a high degree of financial sophistication, and these qualities make him a uniquely valuable member of the compensation committee. The board of directors has reviewed Mr. Richardson's business relationship with the Company that disqualifies him as independent under the definition of the NASDAQ marketplace rules and has concluded that this relationship will not impair his ability to fulfill his responsibilities as a member of the compensation committee.

The compensation committee operates under a written charter adopted by the board of directors which is available on the Company's website at www.sanuwave.com.

Specific responsibilities of the compensation committee include reviewing and recommending approval of compensation of the Company's named executive officers, administering the Company's stock incentive plans, and reviewing and making recommendations to the Company's board of directors with respect to incentive compensation and equity plans.

Nominating and Corporate Governance Committee

The current members of the Company's nominating and corporate governance committee are Barbara M. Henagan, Kevin A. Richardson, II, Thomas H. Robinson, and Ronald M. Sparks, Jr. Mr. Sparks is the chairman of the committee. Pursuant to the Company's Nominating and Corporate Governance Committee Charter, the nominating and corporate governance committee is required to consist of at least two independent directors. If the nominating and corporate governance committee is comprised of at least three members, then, in certain instances one member may be not independent. The board of directors has determined that Ms. Henagan, Mr. Robinson and Mr. Sparks are independent under the applicable NASDAQ marketplace rules and Rule 10A-3 under the Exchange Act. Mr. Richardson is not considered independent due to his holding of securities of the Company and affiliation with a company that holds securities of the Company. The board of directors has determined that, although Mr. Richardson is not independent within the definition of the NASDAQ marketplace rules, exceptional and limited circumstances exist such that the best interests of the Company and its stockholders are served by the membership of Mr. Richardson on the nominating and corporate governance committee. As the founding chairman of the board of directors of the Company, Mr. Richardson has acquired a deep understanding of the Company's operations. The board of directors has reviewed Mr. Richardson's business relationship with the Company that disqualifies him as independent under the definition of the NASDAQ marketplace rules and has concluded that this relationship will not impair his ability to fulfill his responsibilities as a member of the nominating and corporate governance committee.

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

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

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

Compensation Committee Interlocks and Insider Participation

Christopher M. Cashman is the only executive officer that currently serves as a member of the board of directors. None of the Company's executive officers has ever served on the compensation committee, or other committee serving an equivalent function, of any other entity that had one or more of its executive officers serving as a member of the Company's board of directors or compensation committee. None of the members of the compensation committee has ever been an employee of the Company.

Code of Conduct and Ethics

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

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

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

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

Based solely upon a review of the Forms 3, 4 and 5 (and amendments thereto) furnished to us for our fiscal year ended December 31, 2011, we have determined that our directors, officers and greater-than-10% beneficial owners complied with all applicable Section 16 filing requirements.

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table for Fiscal Years 2011 and 2010

The following table provides certain information concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2011 and 2010.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(4)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Christopher M. Cashman Chief Executive Officer and President (principal executive officer)	2011	$385,000	$415,000(1)	-	$1,495,000(2)	-	-	$26,220	$2,321,220
	2010	$350,000	-	-	$668,500(2)	-	-	$23,027	$1,041,527
Barry J. Jenkins Chief Financial Officer (principal financial officer)	2011	$240,547	$182,532(1)	-	-	-	-	$23,197	$446,276
	2010	$233,730	-	-	$384,371(3)	-	-	$22,689	$640,790

(1) This includes two years of bonuses earned (2009 and 2010) which were paid in 2011.
(2) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10. Mr. Cashman was granted options to purchase 1,300,000 shares of common stock at $1.98 per share on October 24, 2011. Mr. Cashman was granted options to purchase 350,000 shares of common stock at $2.00 per share on November 1, 2010.
(3) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10. Mr. Jenkins was granted options to purchase 175,000 shares of common stock at $2.00 per share on

November 1, 2010. Mr. Jenkins was granted options to purchase 20,000 shares of common stock at $4.05 per share on January 29, 2010.
(4) Includes health, dental, life and disability insurance premiums and employer 401(k) matching contributions.

Employment Agreements

Christopher M. Cashman

General Terms. Pursuant to his employment agreement, as amended, Mr. Cashman agreed to serve as the Chief Executive Officer and President of the Company commencing on December 19, 2005 and with no specific duration. Mr. Cashman was entitled to an annual base salary, effective January 1, 2010, of $350,000, and effective January 1, 2011, he was entitled to an annual base salary of not less than $385,000. He is also entitled to a performance and compensation review not less often than annually, at which time compensation may be adjusted as determined by the board of directors; provided that such annual compensation is at least 105% of his previous annual base salary. With respect to each full fiscal year, Mr. Cashman is eligible to earn an annual bonus award of not less than 50% and not more than 200% of his annual base salary based on the achievement of certain performance goals established by the board of directors and generally consistent with the Company's budget and performance goals established for other management employees. Mr. Cashman is also entitled to participate in the Company's employee benefit plans (other than annual bonus and incentive plans). In the event of Mr. Cashman's death during the term of his employment, his heirs will receive a death benefit equal to at least $1,500,000 pursuant to a life insurance policy on the life of Mr. Cashman, the premiums for which are paid by the Company. The employment agreement contains an agreement not to compete, which covers the term of employment and two years thereafter, and a confidentiality provision, which is indefinite.

Equity Arrangements. Upon the execution of his employment agreement, Mr. Cashman was granted options to purchase 201,300 shares of common stock, at an exercise price of $2.92 per share. The options vested and became exercisable in four equal installments on December 19, 2006, 2007, 2008 and 2009. Upon the execution of his employment agreement and his commencement of employment, Mr. Cashman purchased 88,151 shares of common stock, at a purchase price of $2.92 per share.

In addition, upon the execution of his employment agreement, Mr. Cashman was granted three supplemental options to purchase common stock. The terms of the supplemental options were amended on September 15, 2009. The first and second supplemental options each provided him with the right to purchase 139,167 shares of common stock and the third supplemental option provided him with the right to purchase 208,752 shares of common stock. The initial exercise price of the supplemental options is $2.92 per share. The supplemental options fully vested on December 19, 2011.

In addition, upon the execution of the first amendment to his employment agreement dated September 15, 2009, Mr. Cashman was granted the right to receive annually shares of common stock equal to two and one-half times his annual base salary in effect on the date of execution of the first amendment. The shares vest in four equal installments on each twelve month anniversary of the date of grant, provided that the vesting may be accelerated upon the achievement of certain performance goals established by the board of directors. No restricted stock was issued to Mr. Cashman under this provision in 2011 or 2010. Mr. Cashman agreed to forego his right to receive restricted stock under this agreement for fiscal years 2009 through 2011 in exchange for the grant of 1,300,000 stock options on October 24, 2011.

Gross-Ups. In the event that any payment made to Mr. Cashman under his employment agreement or under any other plan maintained by the Company is subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended, the Company will pay Mr. Cashman an additional amount to compensate him for the economic cost of the (1) excise tax of such payment, (2) federal, state and local income tax, and (3) excise tax on the gross-up payment.

Termination. Mr. Cashman’s employment may be terminated by either party at any time and for any reason; provided that Mr. Cashman will be required to give the Company at least 30 days advance written notice of any resignation. If Mr. Cashman is terminated by the Company without cause or resigns with good reason, he will be entitled to receive (1) his base salary through the termination date, (2) any annual bonus earned, but unpaid as of the date of termination for the immediately preceding fiscal year, (3) reimbursement for certain unreimbursed business expenses, (4) such employee benefits to which he may be entitled under the employee benefit plans of the Company, (5) subject to his compliance with certain other provisions of the employment agreement related to confidentiality and the execution of an effective release of claims, a payment equal to 200% of his annual base salary then in effect plus the sum of the cash bonuses paid to him during the previous two fiscal years (but in no case less than 50% of the value of 200% of his annual base salary then in effect), (6) full vesting of all outstanding options and shares of common stock, and (7) a lump sum payment equal to 24 months of the monthly premium cost of providing continuation coverage for Mr. Cashman and his beneficiaries under the Consolidated Omnibus Budget Reconciliation Act of 1986, as amended.

Change of Control. In addition to any other termination benefits that Mr. Cashman may be entitled to receive, if a change of control (as defined below) occurs, then subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, Mr. Cashman will also be entitled to receive 100% accelerated vesting of his options. Mr. Cashman’s right to receive the above change of control termination benefits is not subject to his compliance with the non-compete provisions of his employment agreement. A change in control is defined in the employment agreement as the occurrence of any of the following events: (1) the sale, exchange, lease or other disposition of all or substantially all of the assets of the Company to a person (other than Prides Capital or NightWatch Capital) that will continue the

business of the Company in the future; (2) a merger or consolidation involving the Company in which the voting securities of the Company owned by the shareholders of the Company immediately prior to such merger or consolidation do not represent, after conversion if applicable, more than 50% of the total voting power of the surviving controlling entity outstanding immediately after such merger or consolidation; or (3) any person (other than Prides Capital or NightWatch Capital) is or becomes the beneficial owner, directly or indirectly, of more than 50% of the total voting power of the voting stock of the Company and the representatives of Prides Capital and NightWatch Capital cease to have the ability to elect a majority of the board of directors.

Barry J. Jenkins

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

Equity Arrangements. Upon the execution of his employment agreement, Mr. Jenkins was granted options to purchase 104,677 shares of common stock, at an exercise price of $2.92 per share. The options vested and became exercisable in four equal installments on April 10, 2007, 2008, 2009 and 2010. Upon the execution of his employment agreement and his commencement of employment, Mr. Jenkins purchased 35,089 shares of common stock, at a purchase price of $2.92 per share.

In addition, upon the execution of his employment agreement, Mr. Jenkins was granted three supplemental options to purchase common stock. The terms of the supplemental options were amended on September 15, 2009. The first and second supplemental options each provided him with the right to purchase 34,778 shares of common stock and the third supplemental option provided him with the right to purchase 52,166 shares of common stock. The initial exercise price of the supplemental options is $2.92 per share. The first supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $8.76 per share. Notwithstanding the above, if the common stock closing price equals or exceeds three times the closing price as of the first date that the common stock was listed ($5.25), the first supplemental option will fully vest. In such an event, the exercise price of the first supplemental option will adjust to be the closing price of the common stock on the first date that the common stock was listed ($5.25). The second supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $17.53 per share. Notwithstanding the above, if the common stock closing price equals or exceeds six times the closing price as of the first date that the common stock was listed ($5.25), the second supplemental option will fully vest. In such an event, the exercise price of the second supplemental option will adjust to be the closing price of the common stock on the first date that the common stock was listed ($5.25). The third supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $26.29 per share. Notwithstanding the above, if the common stock closing price equals or exceeds nine times the closing price as of the first date that the common stock was listed ($5.25), the third supplemental option will fully vest. In such an event, the exercise price of the third supplemental option will adjust to be the closing price of the common stock on the first date that the common stock was listed ($5.25).

Termination. Mr. Jenkins' employment may be terminated by either party at any time and for any reason; provided that Mr. Jenkins will be required to give the Company at least 30 days advance written notice of any resignation. If Mr. Jenkins is terminated by the Company for cause or resigns without good reason, he will be entitled to receive his (1) base salary through the termination date, (2) any annual bonus earned, but unpaid as of the date of termination for

the immediately preceding fiscal year, (3) reimbursement for certain unreimbursed business expenses, and (4) such employee benefits to which he may be entitled under the employee benefit plans of the Company. If Mr. Jenkins is terminated by the Company without cause or resigns for good reason, he will be entitled to receive all of the above plus (1) subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, continued payment of the base salary until six months following the date of termination, and (2) continued coverage of him and his beneficiaries under the Company's health insurance programs for a period of up to six months.

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

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. (the "2006 Plan"). On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Amended Plan"). The Amended Plan permits grants of awards to selected employees and directors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include nonstatutory options as well as qualified incentive stock options. The Amended Plan is currently administered by the board of directors of the Company. The Amended 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 Amended Plan are nonstatutory options which vest over a period of up to four 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. The Amended Plan has 5,000,000 shares of common stock reserved for grant.

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

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

On December 31, 2011, there were 2,322,899 shares of common stock available for grant under the Amended Plan. For the years ended December 31, 2011 and 2010, there were 1,300,000 and 545,000 options granted to the Company's executive officers under the Amended Plan, respectively.

Outstanding Equity Awards at 2011 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2011.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market o Payout Value of Unearned Shares, Units or Other Rights That Hav Not Vested ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Christopher	723,600	-	-	$2.92	12/19/2015	-	-	-	-
M.	139,167	-	-	$2.92	12/19/2015	-	-	-	-
Cashman	139,167	-	-	$2.92	12/19/2015	-	-	-	-
	208,752	-	-	$2.92	12/19/2015	-	-	-	-
	350,000	-	-	$2.00	11/01/2020	-	-	-	-
	300,000(1)	1,000,000(1)	-	$1.98	10/24/2021	-	-	-	-
Barry J.	356,037	-	-	$2.92	10/24/2016	-	-	-	-
Jenkins	-	34,778(2)	-	$2.92/$5.25	10/24/2016	-	-	-	-
	-	34,778(3)	-	$2.92/$5.25	10/24/2016	-	-	-	-
	-	52,166(4)	-	$2.92/$5.25	10/24/2016	-	-	-	-
	5,000(5)	15,000(5)	-	$4.05	01/29/2020	-	-	-	-
	175,000	-	-	$2.00	11/01/2020	-	-	-	-

(1) The option was granted October 24, 2011 and vests 300,000 shares at grant date, 325,000 shares at September 15, 2012, 325,000 shares at September 15, 2013, 229,687 shares at September 15, 2014 and 120,313 shares at September 15, 2015.
(2) The supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $8.76 per share. Notwithstanding the above, if the common stock closing price equals or exceeds three times the closing price as of the first date that the common stock was listed ($5.25), the first supplemental option will fully vest. In such an event, the exercise price of the first supplemental option will adjust to be the closing price of the common stock on the first date that the common stock was listed ($5.25).
(3) The supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $17.53 per share. Notwithstanding the above, if the common stock closing price equals or exceeds six times the closing price as of the first date that the common stock was listed ($5.25), the second supplemental option will fully vest. In such an event, the exercise price of the second supplemental option will adjust to be the closing price of the common stock on the first date that the common stock was listed ($5.25).
(4) The supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $26.29 per share. Notwithstanding the above, if the common stock closing price equals or exceeds nine times the closing price as of the first date that the common stock was listed ($5.25), the third supplemental option will fully vest. In such an event, the exercise price of the third supplemental option will adjust to be the closing price of the common stock on the first date that the common stock was listed ($5.25).
(5) The option was granted January 29, 2010 and vests 25% annually for four years.

Director Compensation Table for Fiscal 2011

The following table provides certain information concerning compensation for each director during the fiscal year ended December 31, 2011.

Name(1)	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Barbara M. Henagan	$10,222	-	$38,750	-	-	-	$48,972
John F. Nemelka	-	-	-	-	-	-	-
Kevin A. Richardson, II	-	-	-	-	-	-	-
Thomas H. Robinson	$10,000	-	-	-	-	-	$10,000

Ronald M. Sparks, Jr.	$11,111	-	$40,000	-	-	-	$51,111

(1) Christopher M. Cashman, who is a member of our board of directors, has been omitted from this table since he received no compensation for serving on our board of directors.
(2) The following are the aggregate number of option awards outstanding that have been granted to each of our non-employee directors as of December 31, 2011: Ms. Henagan – 25,000; Mr. Nemelka – 15,000; Mr. Richardson – 15,000; Mr. Robinson – 15,000; and, Mr. Sparks – 25,000.

Discussion of Director Compensation

The Company did not pay any director cash compensation for serving on our board of directors during the fiscal year ended December 31, 2010. With the addition of Barbara M. Henagan and Ronald M. Sparks, Jr. to the board of directors in September 2011, the Company began to compensate its three independent directors at an annual rate of $40,000 each plus $5,000 for being the chair of a board of director's committee. On September 20, 2011, the Company issued 25,000 options to purchase the Company's common stock at $2.95 to non-employee director Ronald M. Sparks, Jr. On September 28, 2011, the Company issued 25,000 options to purchase the Company's common stock at $2.85 to non-employee director Barbara M. Henagan. The September 2011 options were vested when granted and expire ten years after the date of the grant.

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

The following table sets forth certain information, as of March 9, 2012, with respect to the beneficial ownership of the Company's outstanding stock by (i) any holder of more than five percent, (ii) each of the Company's executive officers and directors, and (iii) the Company's directors and executive officers as a group.

Name of Beneficial Owner (1)	Number of Shares Beneficially Owned (2)	Percent of Shares Outstanding
Christopher M. Cashman (3)	2,298,759	10.1 %
Barry J. Jenkins (4)	863,509	4.0 %
Kevin A. Richardson, II (5)	2,892,258	12.9 %
Barbara M. Henagan (6)	30,000	*
Ronald M. Sparks, Jr. (7)	25,000	*
Thomas H. Robinson (8)	15,000	*
John F. Nemelka (9)	11,750	*
David N. Nemelka (10)	3,080,537	13.7 %
Prides Capital Fund I, LP (11)	10,520,077	47.1 %
NightWatch Capital Partners II, LP (12)	2,108,369	10.0 %
All directors and executive officers as a group (7 persons)	6,136,276	24.6 %

* Less than 1% of outstanding shares.

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

(2) "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of March 9, 2012. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.

(3) Includes options to purchase up to 1,860,686 shares of common stock and warrants to purchase up to 8,816 shares of common stock.

(4) Includes options to purchase up to 657,759 shares of common stock and warrants to purchase up to 3,508 shares of common stock.

(5) Includes options to purchase up to 11,250 shares of common stock and warrants to purchase up to 1,440,504 shares of common stock.

(6) Includes options to purchase up to 25,000 shares of common stock.

(7) Includes options to purchase up to 25,000 shares of common stock.

(8) Includes options to purchase up to 15,000 shares of common stock.
(9) Includes options to purchase up to 11,250 shares of common stock.
(10) Based solely on information contained in filings made on schedule 13D, as amended, and on Form 4's with the SEC by the reporting person. Includes warrants to purchase up to 1,566,014 shares of common stock. The principal address of David N. Nemelka is 2662 Stonebury Loop Road, Springville, UT 84663.
(11) Based solely on information contained in filings made on schedule 13D, as amended, with the SEC by the reporting person. Includes warrants to purchase 1,438,088 shares of common stock. The principal business address of Prides Capital Fund, I, LP is 200 State Street, 13th floor, Boston, MA 02109.
(12) Based solely on information contained in filings made on schedule 13D, as amended, with the SEC by the reporting person. Includes warrants to purchase 204,224 shares of common stock. The principal business address of NightWatch Capital Partners II, LP is 5314 River Run Drive, Suite 350, Provo, UT 84604.

Securities Authorized for Issuance Under Equity Compensation Plans

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

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

Other than as described below, for the fiscal year ended December 31, 2011, there were no transactions with related persons required to be disclosed in this report.

On April 8, 2011, we completed a private placement to 28 institutional and individual accredited investors of 2,804,593 shares of our common stock at a purchase price of $3.25 per share, for gross proceeds of $9,114,927. The net proceeds received by the Company were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of our common stock at an initial exercise price of $4.00 per share. The net proceeds from the private placement, following the payment of offering-related expenses, are being used by us for working capital and other general corporate purposes. David N. Nemelka, a greater than 10% shareholder of the Company and the brother of John F. Nemelka, a member of our board of directors, was one of the purchasers in the offering.

On April 4, 2011, the note holders of our amended senior notes (the “Notes”) cancelled the unpaid principal and interest balance of the Notes which totaled $4,413,908 in consideration for the issuance of 1,358,126 shares of our common stock. In addition, in connection with this transaction, we issued to the note holders an aggregate total of 679,064 warrants to purchase shares of common stock at an exercise price of $4.00 per share. Each warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expire after five years. The Notes were held by Prides Capital Fund I, LP and NightWatch Capital Partners II, LP. Kevin A. Richardson, II, who is the chairman of our board of directors, serves as the managing partner of Prides Capital, LLC, an affiliate of Prides Capital Fund I, LP. John F. Nemelka, who is a member of our board of directors, serves as managing principal of NightWatch Capital Advisors, LLC, an affiliate of NightWatch Capital Partners II, LP.

In January 2011, we raised $3,900,334 from a group of accredited investors through the exercise of options they received in 2010 as part of a purchase of a unit which consisted of: (i) one share of common stock, par value $0.001 per share; (ii) a two-year common stock purchase warrant (the “Class D Warrant”) to purchase one share of common stock, at an exercise price of $2.00; and (iii) an option ,which, as amended, expired on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit. Kevin A. Richardson, II, who is chairman of our board of directors, exercised 545,252 options and David N. Nemelka, a greater than 10% shareholder of the Company and the brother of John F. Nemelka, a member of our board of directors, exercised 686,252 options in connection with this transaction.

Between September 30, 2010, and December 7, 2010, we issued 925,000 units to certain accredited investors for an aggregate total purchase price of $1,850,000. Each unit was sold to the new investors at a purchase price of $2.00 per unit. As a result of the offerings, we sold 925,000 units which consisted of 925,000 shares of common stock, 925,000 Class D warrants and 925,000 options, which, as amended, expired on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit. David N. Nemelka, a greater than 10% shareholder of the Company and the brother of John F. Nemelka, a member of our board of directors, purchased 175,000 Units in the offerings for a total purchase price of $350,000.

During 2010, we issued promissory notes totaling $1,750,000 to Kevin A. Richardson, II, our chairman of the board of directors, and $500,000 to David N. Nemelka, a greater than 10% shareholder of the Company and the brother of John F. Nemelka, a member our board of directors. On October 12, 2010, in conjunction with an offering, we

amended the terms of the outstanding promissory notes such that the unpaid principal and interest on each note was exchanged into units. The unpaid principal and interest on the notes to Kevin A. Richardson, II totaled $1,790,504, and this sum was exchanged into a total of 895,252 units which consisted of 895,252 shares of common stock, 895,252 Class D warrants and 895,252 options, which, as amended, expired on January 31, 2011, to purchase another unit at the purchase price of $2.00 per unit. The unpaid principal and interest on the notes to David N. Nemelka totaled $522,504, and this sum was exchanged into a total of 261,252 units which consisted of 261,252 shares of Common Stock, 261,252 Class D warrants and 261,252 options, which, as amended, expired on January 31, 2011, to purchase another unit at the purchase price of $2.00 per unit.

Director Independence

Our board of directors has determined that Barbara M. Henagan, Thomas H. Robinson and Ronald M. Sparks, Jr. qualify as independent directors based on the NASDAQ stock market definition of "independent director." The members of each committee of the board of directors that is an "independent director" can be found in the above descriptions of each standing committee of the board of directors.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table summarizes the fees that we have paid or accrued for audit and other services provided by our principal independent public accounting firm, BDO USA, LLP, for the period April 1, 2011 through December 31, 2011, and HLB Gross Collins, P.C., for the period January 1, 2010 through March 31, 2011:

Fee Category	2011	2010
Audit fees	$124,502	$101,000
Tax fees	15,000	10,000
Audit related fees	-	-
All other fees	-	-
Total fees	$139,502	$111,000

For purposes of the preceding table:

- Audit fees consist of fees for the annual audit of our consolidated financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with statutory and regulatory filings and consents related to capital markets transactions and engagements for those fiscal years.
- Tax fees consist of fees for tax compliance, tax advice and tax planning services for those fiscal years.
- Audit related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit or review.
- All other fees consist of fees for all other products and services.

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

Audit Committee Report

The Company formally adopted the Audit Committee Charter on January 17, 2012. The audit committee oversees the accounting and financial reporting processes of the Company on behalf of the board of directors. Management has primary responsibility for the Company's financial statements, financial reporting process and internal controls over financial reporting. The independent auditors are responsible for performing an independent audit of the Company's

consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). The audit committee's responsibility is to select the independent auditors and monitor and oversee the accounting and financial reporting processes of the Company, including the Company’s internal controls over financial reporting, and the audits of the consolidated financial statements of the Company.

During the first quarter of 2012, the audit committee met and held discussions with management and the independent auditors. In the discussions related to the Company's consolidated financial statements for fiscal year 2011, management represented to the audit committee that such consolidated financial statements were prepared in accordance with United States generally accepted accounting principles. The audit committee reviewed and discussed with management and the independent auditors the audited consolidated financial statements for fiscal year 2011.

In fulfilling its responsibilities, the audit committee discussed with the independent auditors the matters that are required to be discussed by Statement on Auditing Standards No. 61, as amended, Communication with Audit Committees. In addition, the audit committee received from the independent auditors the written disclosures and letter required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent auditor's communications with the audit committee concerning independence, and the audit committee discussed with the independent auditors that firm's independence. In connection with this discussion, the audit committee also considered whether the provision of services by the independent auditors not related to the audit of the Company's financial statements for fiscal year 2011, if any were provided, were compatible with maintaining the independent auditors' independence. The audit committee's policy requires that the audit committee approve any audit or permitted non-audit service proposed to be performed by its independent auditors in advance of the performance of such service.

Based upon the audit committee's discussions with management and the independent auditors and the audit committee's review of the representations of management and the written disclosures and letter of the independent auditors provided to the audit committee, the audit committee recommended to the board of directors that the audited consolidated financial statements for the year ended December 31, 2011 be included in the Company's Annual Report on Form 10-K, for filing with the SEC.

The Audit Committee

Barbara M. Henagan (Chair)
John F. Nemelka
Ronald M. Sparks, Jr.

February 13, 2012

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. All financial statements

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

2. Financial statement schedules

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

3. Exhibits

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

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
SANUWAVE Health, Inc. and Subsidiaries
Alpharetta, Georgia

We have audited the accompanying consolidated balance sheet of SANUWAVE Health, Inc. and Subsidiaries as of December 31, 2011 and the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for the year ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of SANUWAVE Health, Inc. and Subsidiaries at December 31, 2011, and the results of its operations and its cash flows for the year ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ BDO USA, LLP

Atlanta, Georgia
March 14, 2012

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

SANUWAVE Health, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheet of

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

as of December 31, 2010, and the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for the year ended December 31, 2010. SANUWAVE Health, Inc. and Subsidiaries' management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of SANUWAVE Health, Inc. and Subsidiaries as of December 31, 2010, and the results of its operations and its cash flows the year ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As shown in the consolidated financial statements, the Company incurred a net loss of approximately $14,922,000 during the year ended December 31, 2010 and had a working capital deficiency of approximately $7,030,000 at December 31, 2010. As described more fully in Note (1) to the consolidated financial statements, the Company is economically dependent upon future capital contributions or financing to fund ongoing operations. This condition raises substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ HLB Gross Collins, P.C.
Atlanta, Georgia
March 25, 2011

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2011 and 2010

	2011	2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$3,909,383	$417,457
Accounts receivable - trade, net of allowance for doubtful accounts of $74,852 in 2011 and $36,903 in 2010 (Note 2)	81,565	95,549
Inventory (Note 3)	396,284	463,643
Prepaid expenses	162,975	121,084
Due from Pulse Veterinary Technologies, LLC	27,837	45,389
TOTAL CURRENT ASSETS	4,578,044	1,143,122
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4)	51,206	13,386
OTHER ASSETS	3,192	32,253
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 5)	1,533,782	1,840,538
TOTAL ASSETS	$6,166,224	$3,029,299
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$756,657	$1,829,815
Accrued employee compensation	632,333	1,101,410
Accrued expenses (Note 6)	190,583	256,204
Notes payable, related parties (Note 8)	-	4,247,290
Interest payable, related parties (Note 8)	81,864	82,977
Capital lease payable, current portion (Note 12)	4,576	-
Liabilities related to discontinued operations (Note 7)	655,061	655,061
TOTAL CURRENT LIABILITIES	2,321,074	8,172,757
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 8)	5,372,743	5,372,743
Capital lease payable, non-current portion (Note 12)	8,884	-
TOTAL NON-CURRENT LIABILITIES	5,381,627	5,372,743
TOTAL LIABILITIES	7,702,701	13,545,500
COMMITMENTS AND CONTINGENCIES (Note 12)	-	-
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding (Note 10)	-	-
COMMON STOCK, par value $0.001, 50,000,000 shares authorized; 20,907,536 and 14,794,650 issued and outstanding at December 31, 2011 and 2010, respectively (Note 10)	20,908	14,795

ADDITIONAL PAID-IN CAPITAL	62,940,977	43,728,133
ACCUMULATED OTHER COMPREHENSIVE INCOME	10,466	10,902
RETAINED DEFICIT	(64,508,828)	(54,270,031)
TOTAL STOCKHOLDERS' DEFICIT	(1,536,477)	(10,516,201)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$6,166,224	$3,029,299

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Years Ended December 31, 2011 and 2010

	2011	2010
REVENUES	$802,572	$728,446
COST OF REVENUES	261,890	250,326
GROSS PROFIT	540,682	478,120
OPERATING EXPENSES		
Research and development	2,731,059	3,879,146
General and administrative	6,292,950	7,100,621
Depreciation	19,034	829,576
Amortization	306,756	306,757
Write down of assets held for sale (Note 7)	-	169,581
TOTAL OPERATING EXPENSES	9,349,799	12,285,681
OPERATING LOSS	(8,809,117)	(11,807,561)
OTHER INCOME (EXPENSE)		
Transitional services provided to Pulse Veterinary Technologies, LLC	375,000	360,125
Gain on sale of assets	-	6,565
Loss on extinguishment of debt (Notes 8 and 10)	(1,318,781)	(2,693,896)
Interest expense, net	(472,155)	(961,585)
Loss on foreign currency exchange	(13,744)	(66,058)
TOTAL OTHER INCOME (EXPENSE)	(1,429,680)	(3,354,849)
LOSS BEFORE INCOME TAXES	(10,238,797)	(15,162,410)
INCOME TAX BENEFIT (Note 9)	-	239,969
NET LOSS	(10,238,797)	(14,922,441)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(436)	(10,962)
TOTAL COMPREHENSIVE LOSS	$(10,239,233)	$(14,933,403)
LOSS PER SHARE:		
Net loss - basic	$(0.52)	$(1.15)
Net loss - diluted	$(0.52)	$(1.15)
Weighted average shares outstanding - basic	19,624,061	12,924,872
Weighted average shares outstanding - diluted	19,624,061	12,924,872

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

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Years Ended December 31, 2011 and 2010

	Preferred Stock		Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Retained Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balances as of December 31, 2009	-	$-	12,509,657	$12,510	$33,428,902	$(39,347,590)	$ 21,864	$(5,884,314)
Shares issued for cash, related parties	-	-	175,000	175	349,825	-	-	350,000
Shares issued for cash	-	-	750,000	750	1,499,250	-	-	1,500,000
Promissory notes exchanged for shares, related parties	-	-	1,156,504	1,157	4,786,769	-	-	4,787,926
Promissory notes exchanged for shares	-	-	102,326	102	423,528	-	-	423,630
Shares issued for unit option exercise	-	-	101,163	101	202,225	-	-	202,326
Net loss	-	-	-	-	-	(14,922,441)	-	(14,922,441)
Stock-based compensation	-	-	-	-	3,037,634	-	-	3,037,634
Foreign currency translation adjustment	-	-	-	-	-	-	(10,962)	(10,962)
Balances as of December 31, 2010	-	-	14,794,650	14,795	43,728,133	(54,270,031)	10,902	(10,516,201)
Unit options exercised for cash, related parties	-	-	1,231,504	1,231	2,461,777	-	-	2,463,008
Unit options exercised for cash	-	-	718,663	719	1,436,607	-	-	1,437,326
Private placement shares issued for	-	-	2,804,593	2,805	8,464,316	-	-	8,467,121

cash								
Notes payable, related parties exchanged for shares	-	-	1,358,126	1,358	5,731,331	-	-	5,732,689
Net loss	-	-	-	-	-	(10,238,797)	-	(10,238,797)
Stock-based compensation	-	-	-	-	1,118,813	-	-	1,118,813
Foreign currency translation adjustment	-	-	-	-	-	-	(436)	(436)
Balances as of December 31, 2011	-	$-	20,907,536	$20,908	$62,940,977	$(64,508,828)	$ 10,466	$(1,536,477)

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2011 and 2010

	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(10,238,797)	$(14,922,441)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization	306,756	306,757
Accrued interest	166,618	799,712
Depreciation	19,034	829,576
Change in allowance for doubtful accounts	37,949	16,141
Gain on sale of property and equipment	-	(6,565)
Stock-based compensation	1,118,813	3,037,634
Loss on extinguishment of debt	1,318,781	2,693,896
Write down of assets held for sale	-	169,581
Changes in assets - (increase)/decrease		
Accounts receivable - trade	(23,965)	(63,724)
Inventory	67,359	128,946
Prepaid expenses	(41,891)	73
Due from Pulse Veterinary Technologies, LLC	17,552	82,489
Other	29,061	(1,400)
Changes in liabilities - increase/(decrease)		
Accounts payable	(1,073,158)	760,392
Accrued employee compensation	(469,077)	591,505
Accrued expenses	(65,621)	(372,825)
Interest payable, related parties	(1,113)	82,977
NET CASH USED BY OPERATING ACTIVITIES	(8,831,699)	(5,867,276)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of property and equipment	-	7,000
Purchase of property and equipment	(42,302)	-
NET CASH PROVIDED (USED) BY INVESTING ACTIVITIES	(42,302)	7,000
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from unit options exercised, related parties	2,463,008	-
Proceeds from unit options exercised	1,437,326	-
Proceeds from private placement	8,467,121	-
Payments of principal on capital lease	(1,092)	-
Proceeds from promissory notes, related parties	-	2,250,000
Proceeds from promissory notes	-	200,000
Proceeds from sale of capital stock units, related parties	-	350,000
Proceeds from sale of capital stock units	-	1,702,326
NET CASH PROVIDED BY FINANCING ACTIVITIES	12,366,363	4,502,326
EFFECT OF EXCHANGE RATES ON CASH	(436)	(10,962)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,491,926	(1,368,912)

CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	417,457	1,786,369
CASH AND CASH EQUIVALENTS, END OF YEAR	$3,909,383	$417,457
SUPPLEMENTAL INFORMATION		
Cash paid for interest	$324,768	$81,864
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Notes payable, related parties exchanged for capital stock (Note 8)	$4,413,908	$-
Equipment purchased with capital lease	14,552	-
Promissory notes, related parties exchanged for capital stock (Note 10)	-	2,313,008
Promissory notes exchanged for capital stock (Note 10)	-	204,652
TOTAL NON-CASH INVESTING AND FINANCING ACTIVITIES	$4,428,460	$2,517,660

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2011 and 2010

(1) Going Concern

As shown in the accompanying consolidated financial statements, the Company incurred a net loss of $10,238,797 and $14,922,441 during the years ended December 31, 2011 and 2010, respectively, and the net cash used by operating activities was $8,831,699 and $5,867,276, respectively. As of December 31, 2011, the Company had an accumulated deficit of $64,508,828 and cash and cash equivalents of $3,909,383. These operating losses and cash used by operations create an uncertainty about the Company's ability to continue as a going concern. The continuation of the Company's business is dependent upon raising additional financial support. Management's plans are to obtain additional financial support which may include: raising additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, an investment by a strategic partner in a specific clinical indication or market opportunity; selling all or a portion of the Company's assets, liquidating assets, or seeking relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing should provide the necessary funding for the Company to continue as a going concern. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

(2) Summary of significant accounting policies

Description of the business – SANUWAVE Health, Inc. and subsidiaries (the "Company") is an emerging global regenerative medicine company focused on the development and commercialization of non-invasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. The Company's portfolio of products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions. The Company currently does not have any commercial products in the United States. Revenues are from sales of devices and accessories in Europe.

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

Foreign currency translation - The functional currencies of the Company's foreign operations are the local currencies. The financial statements of the Company's foreign subsidiaries have been translated into United States dollars in accordance with ASC 830, Foreign Currency Matters (formerly SFAS No. 52, Foreign Currency Translation.) All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. Translation adjustments are reported as cumulative translation adjustments and are shown as a separate component of accumulated other comprehensive income (loss) in the consolidated statements of stockholders' deficit.

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2011 and 2010

(2) Summary of significant accounting policies (continued)

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

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

Concentration of credit risk and limited suppliers - Management routinely assesses the financial strength of its customers and, as a consequence, believes accounts receivable are stated at the net realizable value and credit risk exposure is limited. For the year ended December 31, 2011, two distributors accounted for 35% and 25% of revenues. For the year ended December 31, 2010, two distributors accounted for 28% and 22% of revenues.

We depend on suppliers for product component materials and other components that are subject to stringent regulatory requirements. We currently purchase most of our product component materials from single suppliers and the loss of any of these suppliers could result in a disruption in our production. If this were to occur, it may be difficult to arrange a replacement supplier because certain of these materials may only be available from one or a limited number of sources. In addition, establishing additional or replacement suppliers for these materials may take a substantial period of time, as certain of these suppliers must be approved by regulatory authorities.

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

	2011	2010
Balance, beginning of year	$36,903	$20,762
Reserve adjustments - increase	39,247	14,720
Write-offs, net of recovery	(1,298)	1,421
Balance, end of year	$74,852	$36,903

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2011 and 2010

(2) Summary of significant accounting policies (continued)

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

Depreciation of property and equipment - The straight-line method of depreciation is used for computing depreciation on property and equipment. Depreciation is based on estimated useful lives as follows: machines and equipment, 3 years; office and computer equipment, 3 years; leasehold improvements, 3 years; furniture and fixtures, 3 years; vehicles, 3 years; and software, 2 years.

Intangible assets - Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over the average life of 11.4 years.

Fair value of financial instruments - The book values of accounts receivable, accounts payable, and other financial instruments approximate their fair values, principally because of the short-term maturities of these instruments. The Company's long-term debt is carried at historical cost, their respective estimated fair values approximate carrying values due to their limited terms.

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

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

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2011 and 2010

(2) Summary of significant accounting policies (continued)

Income taxes - Income taxes are accounted for utilizing the asset and liability method prescribed by the provisions of ASC 740, Income Taxes (formerly SFAS No. 109). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets related to future years, including loss carryforwards, if there is not sufficient evidence to indicate that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in future years.

The Company will recognize in income tax expense interest and penalties related to income tax matters. For the years ended December 31, 2011 and 2010, the Company did not have any amounts recorded for interest and penalties.

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

Loss per share - The Company calculates net income (loss) per share in accordance with ASC 260, Earnings Per Share (formerly SFAS No. 128, Earnings Per Share). Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. To the extent that securities are "anti-dilutive," they are excluded from the calculation of diluted net income (loss) per share. As a result of the net loss for the years ended December 31, 2011 and 2010, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive equity securities totaled 14,390,697 shares and 13,110,928 shares at December 31, 2011 and 2010, respectively.

Comprehensive income – ASC 220, Comprehensive Income (formerly SFAS No. 130, Reporting Comprehensive Income) establishes standards for reporting comprehensive income (loss) and its components in a financial statement. Comprehensive income (loss) as defined includes all changes in equity (net assets) during a period from non-owner sources. The only source of other comprehensive income (loss), which is excluded from net income (loss), is foreign currency translation adjustments.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2011 and 2010

(2) Summary of significant accounting policies (continued)

Stock-based compensation - The Company uses the fair value method of accounting prescribed by ASC 718, Compensation – Stock Compensation (formerly SFAS No. 123(R), Accounting for Stock-Based Compensation) for its employee stock option program. Under ASC 718, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the applicable vesting period of the stock award (generally up to four years).

Research and development - Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to the Company's products in clinical development, such as payments to contract research organizations, clinical investigators, clinical related consultants, contract manufacturer development costs and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs.

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

(3) Inventory

Inventory consists of the following at December 31, 2011 and 2010:

	2011	2010
Inventory - finished goods	$412,291	$539,141
Inventory - parts	113,593	78,202
Gross inventory	525,884	617,343
Allowance for excess and obsolescence	(129,600)	(153,700)
Net inventory	$396,284	$463,643

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(4) Property and equipment

Property and equipment consists of the following at December 31, 2011 and 2010:

	2011	2010
Machines and equipment	$232,848	$199,520
Office and computer equipment	224,600	296,120
Leasehold improvements	67,421	67,421
Furniture and fixtures	24,613	24,613
Vehicles	22,531	22,531
Software	41,872	40,233
Other assets	2,378	5,080
Total	616,263	655,518
Accumulated depreciation	(565,057)	(642,132)
Net property and equipment	$51,206	$13,386

The depreciation charged to operations was $19,034 and $829,576 for the years ended December 31, 2011 and 2010, respectively. Depreciation expense for the year ended December 31, 2010, includes $754,691 related to Ossatron devices more fully described in Note (7). The depreciation policies followed by the Company are described in Note (2).

(5) Intangible assets

Intangible assets consist of the following at December 31, 2011 and 2010:

	2011	2010
Patents, at cost	$3,502,135	$3,502,135
Less accumulated amortization	(1,968,353)	(1,661,597)
Net intangible assets	$1,533,782	$1,840,538

The amortization expense charged to operations was $306,756 and $306,757 for the years ended December 31, 2011 and 2010, respectively. The amortization policies followed by the Company are described in Note (2).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2011 and 2010

(5) Intangible assets (continued)

Amortization expense for the future years is summarized as follows:

Years ending December 31,	Amount
2012	$306,756
2013	306,756
2014	306,756
2015	306,756
2016	306,758
Total	$1,533,782

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

	Amount	Weighted Average Period (Years)
Patents	$3,502,135	$11.4

(6) Accrued expenses

Accrued expenses consist of the following at December 31, 2011 and 2010:

	2011	2010
Accrued legal professional fees	$61,000	$64,531
Accrued clinical site payments	-	82,500
Accrued audit and tax preparation	75,516	89,173
Accrued other	54,067	20,000
	$190,583	$256,204

(7) Discontinued operations

On October 31, 2008, the Company discontinued its Ossatron mobile service business and accordingly displayed the related assets and liabilities of this business as “discontinued operations.” As of October 1, 2009, management determined that the Ossatron device fixed assets and inventory were not likely to be sold within the next twelve months. Therefore, the Ossatron device fixed assets and related parts inventory was reclassified to continuing operations and depreciation on the Ossatron device fixed assets was restarted at October 1, 2009.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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Years Ended December 31, 2011 and 2010

(7) Discontinued operations (continued)

As of December 31, 2010, management determined that it was not probable that the Company would be able to market the used Ossatron mobile service devices due to the age of the devices and changes in the international electrical standards for which the devices are no longer compliant. Therefore, for the year ended December 31, 2010, the Company recorded additional depreciation expense of $201,153 to fully depreciate the Ossatron devices and also recorded an adjustment of $169,581 to fully reserve for the related parts inventory for those devices.

Ossatron related assets consist of the following at December 31, 2011 and 2010:

	2011	2010
Ossatron devices	$4,703,391	$4,837,165
Accumulated depreciation	(4,703,391)	(4,837,165)
Net property and equipment	-	-
Inventory Ossatron device parts	226,081	226,081
Provision for losses and obsolescence	(226,081)	(226,081)
Net inventory	-	-
Total Ossatron assets	$-	$-

The depreciation charged to operations for these Ossatron devices was zero and $754,691 for the years ended December 31, 2011 and 2010, respectively, which is included in depreciation expense in the accompanying consolidated statements of operations and comprehensive loss.

As of December 31, 2011 and 2010, the Company’s liabilities related to discontinued operations were as follows:

	2011	2010
Accrued expenses	$(655,061)	$(655,061)
Liabilities of discontinued operations	$(655,061	