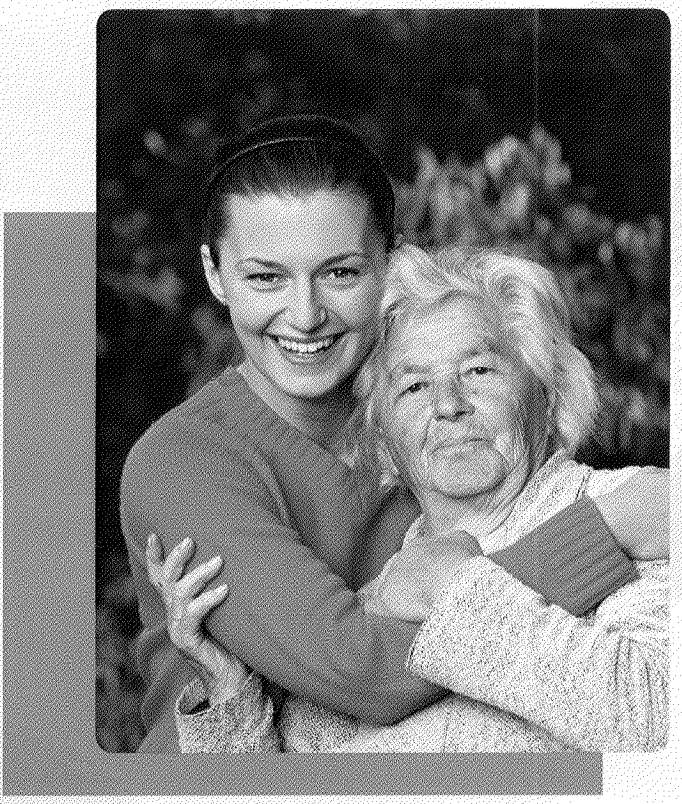
2009 Annual Report

SANUWAVE Health, Inc.

Dear Fellow Shareholders



SANUWAVE® Health produces biological activating devices directed at a broad spectrum of potential indications and attractive markets delivering tissue and musculoskeletal regeneration for many unmet and underserved needs. Pulsed Acoustic Cellular Expression (PACE™) is a platform technology that has the potential to address any medical condition that can benefit from angiogenesis - new blood vessel growth and supply - and carries significant, long-term medical relevance and applicability. We are committed to achieving major value creation for the future patients of our products, our medical professional customers and for you, our shareholders.

The decisions we made and the accomplishments achieved in 2009 have focused, strengthened and positioned SANUWAVE to efficiently and clearly address the multiple, large opportunities ahead of us. We have now created a lean, responsive organization focused on clear, concise action items within our long-term, strategic plan. We also continue to make significant preclinical and clinical progress to strengthen our basic science understanding, as well as to move our product candidates forward in the pipeline to commercialization.

2009 Important Steps for SANUWAVE

Neared enrollment completion of our Phase III pivotal Investigational Device Exemption ("IDE") dermaPACE™ wound care study on Diabetic Foot Ulcers (DFU).

Preclinical findings led by Dr. Maria Siemionow at Cleveland Clinic of microcirculatory effects of PACE™ technology and evidence of proangiogenic growth factors immediately after PACE™ treatment in support of tissue regeneration observations were highlighted in an oral presentation titled "Pulsed Acoustic Cellular Expression" at The 10th Annual Wound Healing: Science and Industry Meeting.

Consolidated and streamlined our international operations back to corporate headquarters in Alpharetta, GA.

Achieved ISO Certification of our United States operation and invested in internal research and development capabilities.

Divested our veterinary product line in order to focus on our human clinical opportunities and upcoming commercialization activities.

Recent Published Research Highlights

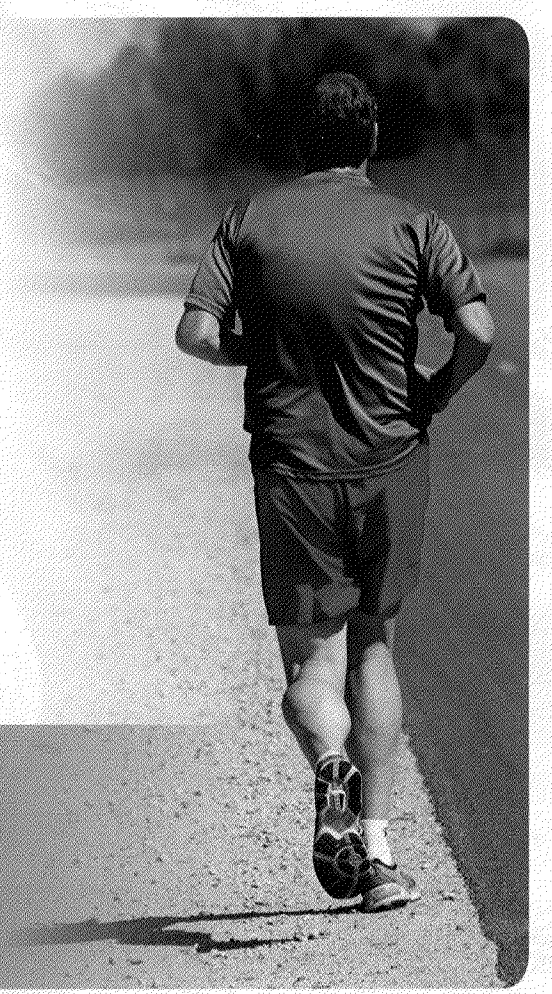
Dr. Myron Spector, PhD, Professor of Orthopaedic Surgery (Biomaterials) at Harvard Medical School, Director of Orthopaedic Research at Brigham and Women's Hospital and Director of Tissue Engineering at VA Boston Healthcare System, presented his orthopedic tissue regeneration research titled "Extracorporeal Shock Wave Stimulation of Osteoprogenitor Cells" at 2009 International Bone-Tissue-Engineering Congress ("Bone-Tec") showing the promise of PACE™ in the stimulation of autogenous sources of progenitor stem cells for harvest and re-transplantation in bone tissue engineering.

The paper titled, *Extracorporeal Shock Waves, a New Non-Surgical Method to Treat Severe Burns*, appeared as an e-publication ahead of print in BURNS (www.burnsjournal.com), and detailed the successful use of PACE™ protocols with the dermaPACE™ device for the treatment of severe burns, including deep partial and full thickness burns. Between January and May 2009, patients with second and third degree burns received dermaPACE™ treatments of 500 impulses on days 3 and 5 after their injury. Burns healed uneventfully within 15 days for 12 out of 15 patients (80%), 2 patients required grafting and 1 patient was lost to follow up. No side effects were observed.

This study is important because approximately 27 million burn cases requiring professional treatment occur worldwide each year, according to the Wound Care Markets, 2nd Edition, Vol II. Burns: Market Report, resulting in a worldwide burn treatment market forecasted to reach $2.6 billion in 2011. Our dermaPACE™ device has successfully treated burns safely and cost effectively in Europe, producing excellent results and in many cases, precluded additional patient trauma due to surgery and grafting.

A journal article titled *Extracorporeal Shock Wave Therapy for Nonunion of the Tibia*, was published in the March 2010 issue of the Journal of Orthopedic Trauma. Based on the results of the study, the authors suggested that non-invasive Extracorporeal Shock Wave Technology (ESWT) applied with SANUWAVE's Ossatron® device with one treatment session of 4,000 pulses followed by fracture immobilization resulted in an 80% rate of healing of the nonunion bone fractures (incomplete fracture healing) as assessed by both clinical and radiographic means.

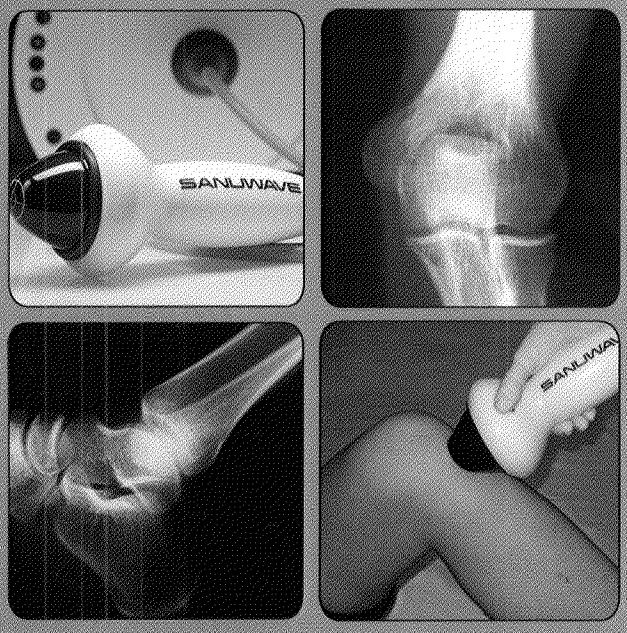
SANUWAVE expects to introduce a new commercial device to European markets called the orthoPACE™ during the second quarter of 2010 that is capable of treating in an equivalent energy range utilized in this study. The orthoPACE™ has a compact, portable design and allows for treatments to be performed by a single operator in both the hospital and office setting. SANUWAVE's strategy for orthoPACE™ in the United States is to focus our clinical efforts and FDA submissions on the $4.2 billion orthopedic repair market.

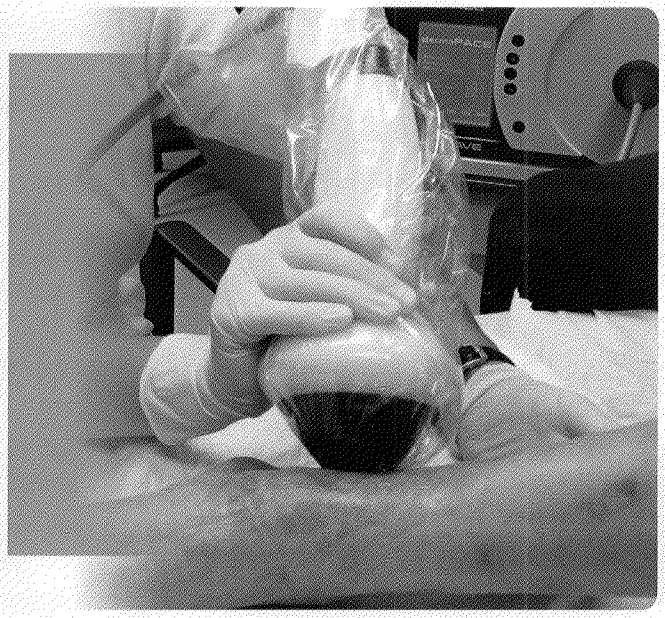


We believe there are limited biologically advanced treatments that directly and reproducibly stimulate healing processes in the areas in which we are focusing, particularly for wound care and repair of certain types of musculoskeletal conditions.

"SANUWAVE strives to bring to market safe and effective, non-invasive technologies in regenerative medicine for the repair and regeneration of tissue, musculoskeletal and vascular structures. We believe we have a robust research and development pipeline, experienced management and research teams, and broad patent protection. As a public company we will likely have more access to the capital markets to help further the development and commercialization of our products."

Christopher M. Cashman
President and CEO, Director





Financial Realities

For the year ended December 31, 2009, we reported a net loss of $6.2 million, or ($0.52) per diluted share, compared to a net loss of $9.4 million, or ($0.86) per diluted share, for the same period in 2008. The net loss for the year ended December, 2009 includes the gain, net of taxes, on the sale of the veterinary product line in June, 2009 of $1.5 million.

The Company ended 2009 with $1.8 million of cash and cash equivalents compared with $0.5 million as of December 31, 2008.

SANUWAVE will continue to work in a capital-constrained environment which will demand aggressive action in the management of capital and expenses in all areas of our corporate and operational functions. We will continue to proactively seek out appropriate opportunities to improve our financial position to insure that our technology and efforts are funded so we may capitalize on the significant opportunities before us.

We have initiated cost-reduction measures, as outlined previously, such as consolidating operations, selling non-core assets and right-sizing our staff as well as rationalizing our major capital expenditures and clinical efforts to coincide with our strategic vision and time line. We will continue to be financially prudent in managing our business as we bring our product candidates to commercialization in an effective and efficient manner.

Wound care market is ready for new innovation with a strong value proposition.

We believe that our lead wound care product candidate, dermaPACE™, represents an opportunity to significantly decrease overall health care costs, significantly increase wound care outcomes over current treatments and deliver a less burdensome treatment protocol for health care providers, patients and payers.

The Advanced Medical Technology Association ("AdvaMed") estimates that the management and treatment of chronic and complex wounds in the United States costs $20 billion annually. According to the American Diabetes Association (the "ADA"), 23.6 million people in the United States have diabetes, 57 million are pre-diabetic and 15% of people with diabetes will acquire a non-healing ulcer in their lifetime. AdvaMed states that over 1.5 million diabetic foot ulcers occur annually, are a recurrent condition and lead to over 82,000 amputations each year, at a direct and indirect cost ranging from $20,000 to $60,000 per patient.

Orthopedics is an expanding frontier as conditions beg for new, non-invasive, biological activating and cost effective approaches.

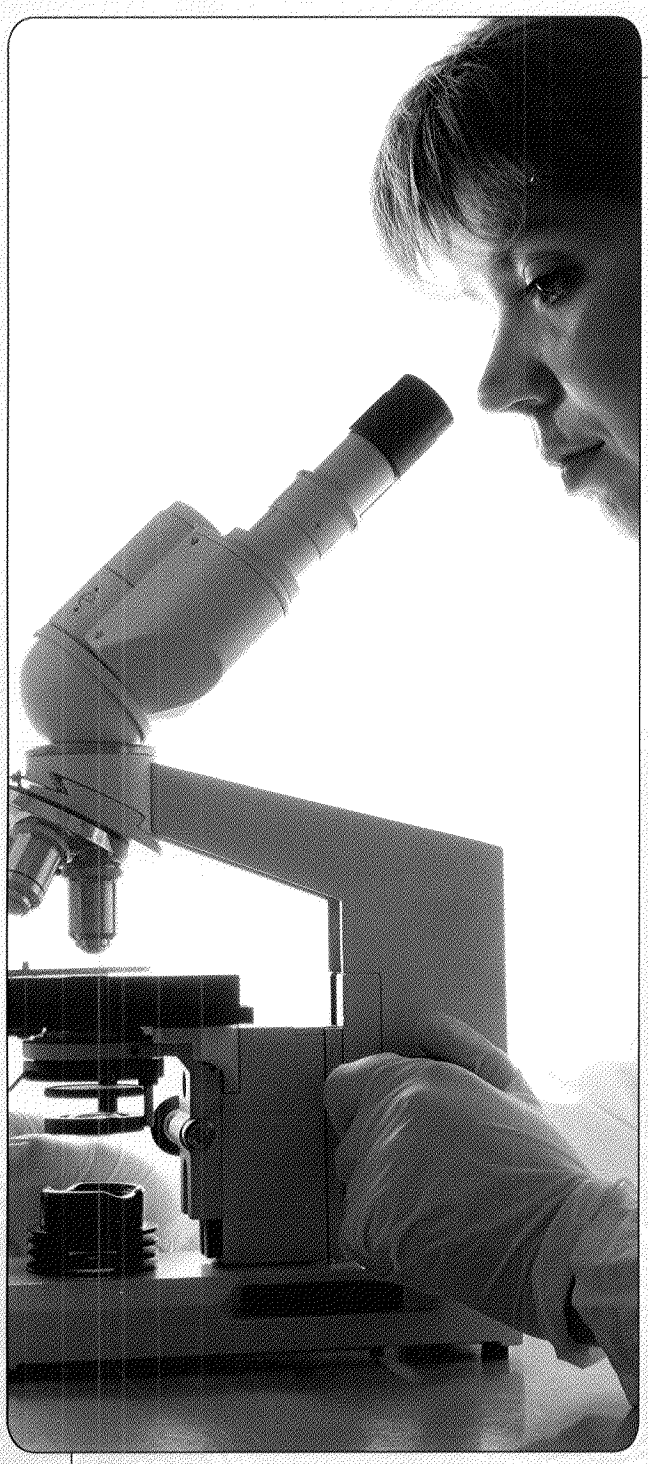
Globally, 135 million people are diagnosed with arthritis, including 32.9 million adults in the United States. Osteoarthritis includes the mechanical break down of cartilage and joint surfaces. Advanced arthritis often requires surgery and joint replacement in 30% of patients. There are 500,000 joint replacements per year in the United States costing $15.2 billion per year.

Also 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 nonunion among these fractures is between 2.5% and 10.0% depending on the fracture type, location and risk factors such as diabetes, smoking history or other systemic diseases.

Our future pipeline, including plastic and aesthetic uses, shows the applicability of PACE™ across a broad spectrum of uses.

We believe our PACE™ technology has potential in plastic/cosmetic procedures based on its unique mechanism of action. We also believe that current statistics, demographic growth, the continued growth in minimally-invasive procedures of the skin and an elective pay market are all positive reasons for us to continue developing protocols and studying the effects of our technology on aesthetic and plastic medical needs. A procedural survey conducted by the American Academy of Cosmetic Surgery says more than 17 million cosmetic surgery procedures were performed in the United States in 2009 – an eight percent (8%) increase in procedures by AACS members since 2008. We believe that our PACE™ technology is well suited for various applications due to its stimulation of a broad spectrum of cellular events critical for the initiation and progression of healing and tissue regeneration.

SANUWAVE is also currently investigating the ability of PACE™ to facilitate spine fusion in several pre-clinical studies spear-headed by Dr. Ching-Jen Wang at The Chang Gung Memorial Hospital in Kaohsiung, Taiwan and has been shown to be safe and effective in a pilot, rabbit model. We plan to create a strategic relationship to develop this indication and bring it to the global, commercial markets.



"The mechanism of action of PACE™ technology is a multi-factorial process. Its direct effects on microcirculation, leukocyte activity and tissue regeneration through induced pro-angiogenic growth factor production, improved microcirculation and positive inflammatory responses create a favorable healing environment that is capable of long-term tissue and bone sustainability. Potential exists for broad application of PACE™ technology due to this novel mechanism of action."

Maria Siemionow, MD, PhD, DSc
Professor of Surgery
Director, Plastic Surgery Research
Head, Microsurgery Training
Cleveland Clinic

2010 will be a transformational year.

We are energized by the prospects for 2010. This is a year that will see SANUWAVE take important steps toward achieving our goal of becoming the most respected and leading bio-regeneration company in the wound care, orthopedics and plastic surgery marketplaces. We expect the results of our ongoing dermaPACE™ DFU Phase III pivotal clinical trial to be available in the fourth quarter of this year. With a successful outcome of that trial, we will have surpassed one of our first key milestones for transforming SANUWAVE from a developmental entity to a commercial company by taking the immediate next steps to gain FDA approval and launch dermaPACE™ in the United States in 2011.

Looking ahead, we will focus on the following priorities for 2010:

Complete enrollment and patient follow-up in the dermaPACE™ pivotal trial, compile the data package and submit the clinical portion of the regulatory filing to FDA by the end of the year;

Assuming the FDA accepts our proposed modular PMA submission for our dermaPACE™ DFU PMA, we expect to submit both packages of the quality and manufacturing modules in the second and third quarters, respectively, and address any questions the FDA may have;

Improve our capital position to fund our future growth and development;

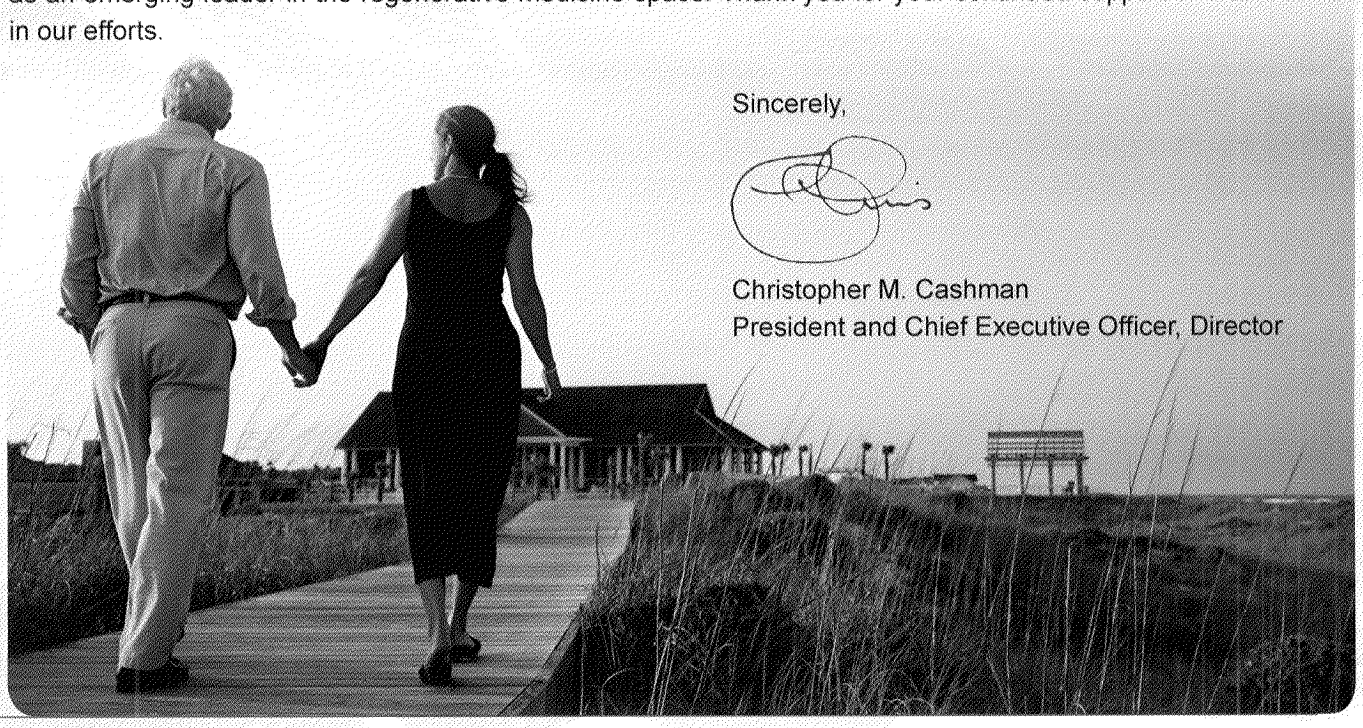
Achieve approval for orthoPACE™ in Europe and begin the commercialization process of the product by expanding into new distribution partnerships and educating the marketplace on its applications;

Continue clinical development efforts on new product candidates that address unmet needs in the United States' wound care market, specifically burns, and venous and complex, chronic ulcers and;

Continue product and clinical development efforts for sports medicine and plastic/aesthetic opportunities.

We are very encouraged by our significant progress to date. We continue to build strong relationships in the clinical and medical community. Terrific momentum is mounting with the growing awareness of the full potential of PACE™. We believe that we will offer the health care community and their patients a unique solution to demanding medical problems at a reasonable cost.

We look forward to achieving our goals for this year and continuing to lay the foundation to establish SANUWAVE as an emerging leader in the regenerative medicine space. Thank you for your continued support and confidence in our efforts.



Sincerely,

Christopher M. Cashman
President and Chief Executive Officer, Director

Directors and Senior Management

Directors

Kevin A. Richardson, II
Chairman

John F. Nemelka
Director

Christopher M. Cashman
Director

Thomas H. Robinson
Director

Senior Management

Christopher M. Cashman
Chief Executive Officer
President and Director

Barry J. Jenkins
Chief Financial Officer

Anne A. Stefurak, RN, CPC, CPC-H
Vice President of Medical Policy and Reimbursement

Bernie M. Laurel
Vice President of Sales and Marketing

Iulian C. Cioanta, PhD
Vice President of Research and Development

Peter A. Stegagno
Vice President of Operations, Regulatory / Clinical

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2009

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

For the transition period from _____ to _____

Commission File Number 000-52985

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

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

(678) 581-6843
(Registrant's telephone number, including area code)

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

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

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

Common Stock, $0.001 par value per share

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§2229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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

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

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

The registrant is unable to determine the aggregate market value of its common stock held by non-affiliates as of June 30, 2009. The registrant's common stock is quoted on the Over-The-Counter Bulletin Board but there was no trading volume as of June 30, 2009.

As of March 16, 2010, there were issued and outstanding 12,509,657 shares of the registrant's common stock.

SANUWAVE Health, Inc.

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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," "estimate," "predict," "potential" and "continue," the negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in this report, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Other risks and uncertainties are and will be disclosed in the Company's prior and future Securities and Exchange Commission 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.

PART I

Item 1. BUSINESS

Overview

We are an emerging medical technology company focused on the development and commercialization of non-invasive, biological response activating devices in the regenerative medicine area 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 through our legacy products that our PACE technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States Food and Drug Administration (the "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 and Evotron® devices in Europe. Our lead product candidate 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.

With the divestiture of our worldwide Versatron® veterinary product line in June 2009, we are now entirely focused on developing our PACE technology to stimulate healing in:

(1) wound conditions, including diabetic foot ulcers, burns, pressure sores and other skin eruption conditions;

(2) orthopedic/spine applications, such as speeding the healing of fractures (including non-union 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;

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

(4) cardiac procedures for removing plaque due to atherosclerosis and improving heart muscle performance.

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 for the last nine years, demonstrates the safety, clinical utility and efficacy of our product candidates. 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.

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 non-invasive 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.

According to the National Bureau of Economic Research, the United States economy has been in a recession since December 2007. This economic downturn and the ensuing instability of markets have impacted us in the short term by making it difficult to raise the necessary capital to fund our research and development programs, as well as the infrastructure needed to plan for follow-on programs, upcoming regulatory submissions, product approvals, market launches and insurance reimbursement interactions. Furthermore, our general business strategy may be further adversely affected if the recessionary economic conditions persist for an extended period of time or deteriorate further. For example, the economy may impact the demand for elective medical procedures that we are targeting with our product candidates, or may impact the pricing of our products. However, since our anticipated product launch for our lead product candidate remains over a year away, the impact of the current recession on commercial markets for that product remains uncertain.

Pulsed Acoustic Cellular Expression ("PACE") Technology

Our PACE product candidates, including our lead product candidate, dermaPACE, utilize high energy, acoustic pressure waves that are delivered in the "shockwave" acoustic spectrum to enhance new blood vessel formation, and soft tissue and bone regeneration. PACE pressure waves combine compressive and tensile stresses on cells and structures to promote an inflammatory response in musculoskeletal and soft tissue, resulting in microcirculatory improvement, including the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and subsequent regeneration of tissue. PACE waves are different from other forms of acoustic energy, such as ultrasound, in that the wave front, in which the compressive forces exist, is a region of sudden and forceful change in stress, density and temperature, which positively regulates the inflammatory response and reinitiates the cellular proliferation phases, allowing the body's own healing response to reinitiate or be enhanced. We believe that our PACE technology is well suited for various applications due to its stimulation of a broad spectrum of cellular events critical for the initiation and progression of healing.

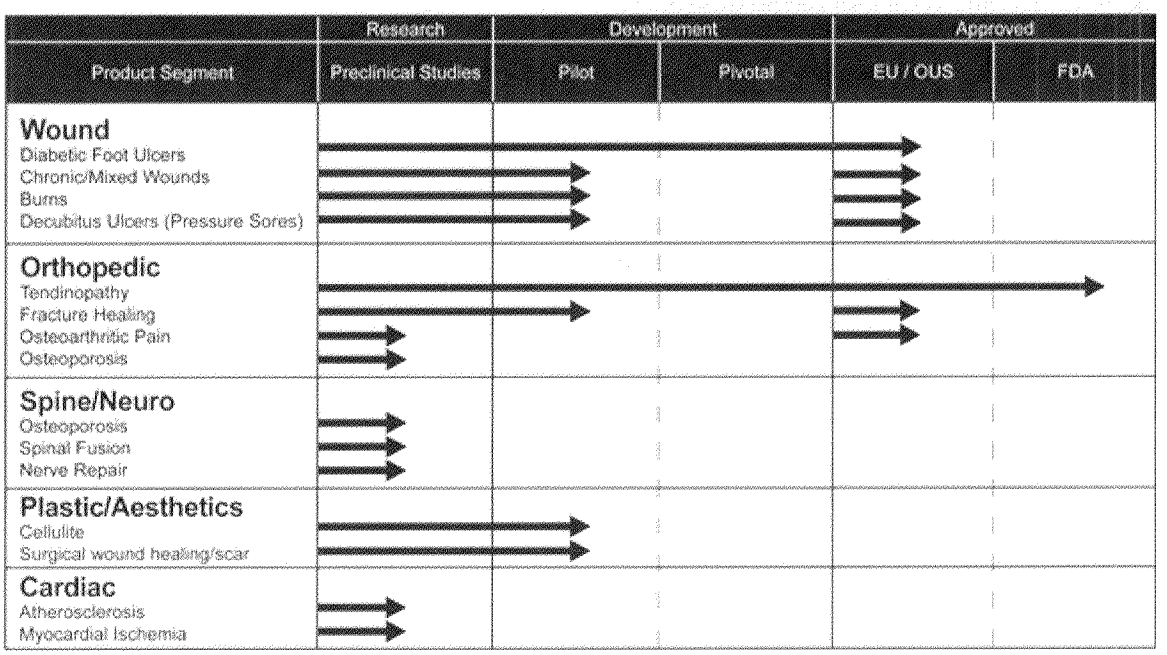
Components of our product candidates have been cleared and approved by the United States Food and Drug Administration (the "FDA") for marketing in other applications. High energy, acoustic pressure waves or "shockwaves" are the primary component of our previously developed product, Ossatron, which was approved 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.

In addition, our dermaPACE product candidate has received the European Conformity Marking ("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.

We are enrolling patients in a multi-site randomized, double-blind, sham controlled FDA investigational device exemption ("IDE") clinical trial for dermaPACE in the treatment of diabetic foot ulcers. We expect to complete the last phase of the clinical trial enrollment, follow-up and clinical trial data un-blinding in 2010 and to submit to the FDA for regulatory approval in 2011. Our plan is to begin commercializing dermaPACE in the United States by 2012.

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 from Europe. These discussions will focus on building knowledge of dermaPACE and building relationships. We will also begin the process of obtaining a new Category III Current Procedural Terminology ("CPT") code for dermaPACE for Medicare tracking purposes, which is a requisite first step in obtaining medical reimbursement for dermaPACE. 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 required treatments.

We have a development pipeline of product candidates. The following chart depicts our development interests at the research and/or development stage, as well as the regulatory approval for the commercialization stage.



We have established clinical, manufacturing and development relationships and multiple regulatory pathways to product development. We believe that these relationships and pathways, coupled with the well-characterized biologic response, history of safe use and clinically-proven efficacy of our PACE technology, all position us to become a leader in the development and commercialization of non-invasive, biological response devices for the repair and regeneration of tissue, musculoskeletal and vascular structures that will capitalize on the growing market for these products in wound healing, orthopedic/spine, plastic/cosmetic and cardiac applications. Although the results of our studies have been positive to date, we cannot provide any assurance that we will be successful in developing, obtaining regulatory approval for, or commercializing our current product candidates, or that we will do so in a timely fashion.

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet clinical needs in large market opportunities. Currently, there are limited biological or mechanical therapies to stimulate 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 PACE technology is well positioned to address many of these issues. We believe that our PACE technology, in promoting tissue regeneration, can be effective in a broad array of applications and address unmet medical needs in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions.

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. The Advanced Medical Technology Association ("AdvaMed") estimates that the management and treatment of chronic and complex wounds costs the United States $20 billion annually. According to the American Diabetes Association (the "ADA"), 23.6 million people in the United States have diabetes, 57 million are pre-diabetic and 15% of people with diabetes will acquire a non-healing ulcer in their lifetime. AdvaMed states that over 1.5 million diabetic foot ulcers occur annually, are a recurrent condition, and lead to over 82,000 amputations each year, at a direct and indirect cost ranging from $20,000 to $60,000 per patient. AdvaMed estimates that chronic leg wounds (ulcers) account for the loss of two million workdays per year, at a cost of approximately $300 million in lost productivity. We believe that our dermaPACE device represents an opportunity to significantly decrease overall healthcare costs, while providing wound care outcomes that are significantly better than current treatments.

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. 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 non-invasive 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 simple protocol of four treatments over a two week period, 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. dermaPACE's non-invasive treatment is designed to elicit the body's own healing response.

Our clinical experiences have demonstrated the ability of dermaPACE to promote wound healing, improve healing time and help prevent chronic conditions, such as diabetic foot ulcers, from leading to amputation. Our dermaPACE product candidate has been used safely for various types of acute and chronic wounds. Our clinical case studies completed to date using dermaPACE have shown full wound closure in at least 60% of those patients treated at 12 weeks for chronic diabetic foot ulcers, conditions that have been previously unresponsive to available treatments, representing as much as a 50% closure rate improvement over other existing competitor treatment options.

In response to positive European clinical results and what we believe is a need for non-invasive advanced burn care modalities, we expect to initiate a Phase II, IDE study in the United States in 2010 using dermaPACE for the treatment of burns. Approximately 27 million burn cases requiring professional treatment occur worldwide each year resulting in a worldwide burn treatment market forecasted to reach $2.6 billion in 2011, according to the *Wound Care Markets, 2nd Edition, Vol II. Burns: Market Report.*

According to AdvaMed, Centers for Medicare & Medicaid Services and our internal projections for dermaPACE, the United States advanced wound healing market was estimated at $5 billion in 2008, which includes diabetic foot ulcers, pressure sores, burns and traumatic wounds, and chronic mixed leg ulcers.

Developing Product Opportunities

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 biologically advanced treatments that directly and reproducibly stimulate healing processes in the areas in which we are focusing, particularly for wound care and repair of certain types of musculoskeletal conditions.

With the success of negative pressure wound therapy devices in the wound care market over the last ten years and the recognition of the global epidemic associated with 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 mechanical, biological response activating devices that are applied non-invasively and seek to stimulate the body's own capabilities for regeneration of tissue at injury sites in a cost-effective manner.

Orthopedic and Spine

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.

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. SANUWAVE, through its legacy device Ossatron®, has had a long history in the sports medicine field that generally refers to the non-surgical and surgical management of cartilage, ligament and tendon injuries. 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 stimulate healing and regenerate these tissues, many of these injuries will result in a degree of permanent impairment and chronic pain. Prior investigations and new pre-clinical work indicate that PACE can stimulate the various cell types that constitute cartilage, ligament and tendon. PACE historical data suggest PACE will continue to be an important adjunct to the management of sports medicine injuries. We plan to introduce into the European Community (EU) our next generation device, orthoPACE®, during the first half of 2010.

Spinal fusion is a surgical technique performed to correct an unstable part of the spine by joining two or more vertebrae, such as degenerative disc disease (DDD), 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 severe and potentially life-threatening side effects, particularly when used in the neck region. We are currently investigating the ability of PACE to facilitate spine fusion in several pre-clinical studies and PACE has been shown to be safe and effective in a pilot, rabbit model.

Plastic and Aesthetic

We believe our PACE™ technology has potential in plastic/cosmetic procedures based on its unique mechanism of action. We also believe that current statistics, demographic growth, the continued growth in minimally-invasive procedures of the skin and an elective pay market are all positive reasons for us to continue developing protocols and studying the effects of our technology on aesthetic and plastic medical needs. A procedural survey conducted by the American Academy of Cosmetic Surgery ("AACS") says more than 17 million cosmetic surgery procedures were performed in the United States in 2009 — an eight percent (8%) increase in procedures by AACS members over 2008. We believe that our PACE™ technology is well suited for various applications due to its stimulation of a broad spectrum of cellular events critical for the initiation and progression of healing and tissue regeneration.

Cardiac

According to the American Heart Association, myocardial ischemia in the United States continues to be a major problem, with more than six million Americans living with it, and the World Health Organization states that heart attacks are the leading cause of death globally. With the continued advances of minimally invasive procedures in heart surgery and angioplasties, we will continue to develop and look for strategic partners to help develop our PACE technology to address what we believe to be are unmet cardiac needs.

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, elbow and bone indications to enter the advanced wound care market with innovative treatments.

The key elements of our strategy include the following:

- ***Develop and commercialize non-invasive 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, orthopedics/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 sales force utilizing direct representatives 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 surgeon relationships. Outside the United States, we intend to utilize our distributor relationships for product introduction and adoption in local markets.

Scientific Advisors

We have established a network of advisors that brings expertise in wound healing, orthopedics, cosmetic, 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 $74,000 and $126,000 for the years ended December 31, 2009 and 2008, respectively.

Sales, Marketing and Distribution

We intend to establish a direct sales force in the wound care market that will market our products. The direct sales forces will be managed by our 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 surgeon and care giver customers. We expect to have a 75-person sales force in the United States by the end of 2013 that will represent our initial dermaPACE commercial efforts.

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.

Reverse Merger Transaction

On September 25, 2009, the Company (formerly named Rub Music Enterprises, Inc.) and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of the Company (the "Merger Sub") entered into a reverse merger agreement (the "Merger Agreement") with SANUWAVE, Inc. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, Inc. with SANUWAVE, Inc. as the surviving entity (the "Merger"). In connection with the Merger, the Company acquired 100% of the outstanding capital stock of SANUWAVE, Inc. and the stockholders of SANUWAVE, Inc. received 11,009,657 shares of the Company's common stock, warrants to purchase 1,106,627 shares of the Company's common stock at $4.00 per share, and warrants to purchase an additional 1,106,627 shares of the Company's common stock at $8.00 per share. In addition, in connection with the Merger, certain stockholders of the Company agreed to cancel all of their shares of common stock of the Company, except for 1,500,000 shares of common stock, for an aggregate price of $180,000 (the "Share Repurchase"). At the time of the Merger, the Company had 1,500,000 warrants outstanding to purchase the Company's common stock at $4.00 per share.

As a result of the Merger and Share Repurchase, the stockholders of SANUWAVE, Inc. controlled approximately 88% of the Company's outstanding common stock, holding 11,009,657 of the 12,509,657 outstanding shares, and SANUWAVE, Inc. was considered the accounting acquirer in the Merger. As a result of the Merger, the Company's operations are now focused in global medical technology and the Company is no longer a shell company.

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; wherefore, our generator boxes are manufactured in accordance with applicable quality standards (EN ISO 13485 applicable industry and regulatory standards). From time to time, we use contract facilities to complete the manufacturing, packaging and generator box testing for our products and applicator kits, as applicable. We produce the applicator heads and kits for our products, and perform the final product testing and certifications internally.

Our two facilities in Alpharetta, Georgia consist of approximately 20,000 square feet in total, and provide office, research and development, production and quality control 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 and services 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 selected 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 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 thirteen issued United States patents and eight issued foreign patents. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations, 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 two United States provisional applications, ten United States non-provisional applications and ten 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. Under issued United States Pat. No. 6,972,116, directed to particular compositions of shockwave device electrodes, we receive a perpetual, exclusive and royalty-free license in the Ortho Field and a non-exclusive license in all other fields other than the Litho Field (reserved exclusively to HealthTronics). We also receive 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.

As part of the sale of the veterinary business, 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.

A Swiss-based competitor, SwiTech Medical AG ("SwiTech") recently challenged one of our issued United States patents and three of our issued German patents. The United States Patent and Trademark Office (the "USPTO") notified us that an ex parte reexamination request was filed on May 19, 2009, against our United States Pat. No. 6,080,119, but the USPTO subsequently rejected and terminated processing of SwiTech's request without further action. This United States reexamination request followed SwiTech's nullity action brought against the foreign counterpart German Pat. No. DE 197 18 512. The German Federal Patent Court ordered a partial revocation of claims of the German patent directed to device and process claims for a gas suppression catalyst used with shockwave device electrodes and upheld a narrower patent claim directed to a combination of a dispensing container for a catalyst that suppresses the electrolytic creation of gas caused when the high voltage is applied to shockwave device electrodes. Following an assignment to HealthTronics, with a non-exclusive license back to us, HealthTronics filed an appeal to the partial revocation decision of German Pat. No. DE 197 18 512 that remains pending.

SwiTech also filed a partial nullity action against two claims (out of ten total claims) of German Pat. No. DE 197 18 513. On August 6, 2009, the German Federal Patent Court held that the challenged claims, directed to a shockwave device with a pressure-tight liquid volume including electrodes with a spark gap (claim 1) and further with an additive improving conductivity and/or recombination of electrolytic gas (claim 6), were revoked. The unchallenged claims directed to certain further combinations of electrode and reflector electrical contact, configurations and additive remain in the issued patent. A final written decision was issued without further appeal, and the share of court costs allocated to us by the German Patent Court was approximately $24,000.

SwiTech further filed a partial nullity action against seven claims (out of twenty-two total claims) of German Pat. No. DE 197 18 511. The German Federal Patent Court decided during oral hearing on February 11, 2010 to amend the challenged claims directed to a detachable therapy head to shockwave supply unit to further include a limitation of at least two different therapy heads being mechanically and electrically connected to a supply unit. No claims were revoked from the issued patent. We have not received a formal written decision of the German Federal Patent Court or determined whether we will appeal the decision. German patent counsel advised that absent further appeal, our share of remaining legal and court costs is estimated to be approximately $23,000.

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, lengthy governmental proceedings, 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 product recognition. We have trademark registrations for SANUWAVE® in the United States, European Community, Canada, Japan, Switzerland, Taiwan and under the Madrid Protocol. We have filed pending trademark applications for dermaPACE™ in the United States and Canada and received registrations in the European Community, Japan, South Korea, Switzerland, Taiwan and under the Madrid Protocol. We have received trademark registrations for PACE™ and Pulse Acoustic Cellular Expression™ in the European Community, Hong Kong, Singapore, Switzerland, Taiwan and have pending applications in Canada, China and the United States. We have filed pending applications for orthoPACE™ in the United States and European Community, and evoPACE™ and angioPACE™ in Australia, Canada, European Community, Switzerland and the United States. We also maintain trademark registrations for the marks Ossatron® (United States and Germay), Evotron® (United States, Germany and Switzerland), Evotrode® (Germany and Switzerland), Healing Today. Curing Tomorrow.® (United States), 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 device companies are highly complex and uncertain. The combination product and medical device industries are 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 is dramatically underserved. Current technologies developed by Kinetic Concepts, Inc. ("KCI"), Smith & Nephew plc, ConvaTec, Johnson & Johnson, Molnlycke Health Care US, LLC and 3M Company manage wounds, but, in our opinion, do not impact the biologic factors to promote healing like our PACE technology. 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 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 revenue of $1.4 billion from the V.A.C. in 2009.

The tissue market for regenerative medicine include companies that provide human allograft products and services such as Cook, Integra LifeSciences Holdings Corporation, LifeCell (acquired by KCI), C.R. Bard, Inc., Systagenix Wound Management (US), Inc., and Tissue Science Laboratories, plc. 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 also may 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 would 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 which are Class II or Class III will 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. Other product candidates alone should be eligible for clearance via the 510(k) route with use of more generic labeling. For example, we may submit and obtain clearance for a 510(k) application for clearance of a product for "temporary improvement in blood circulation" utilizing predicate devices.

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 the 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, or QSR, 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.

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, or 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 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.

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, or 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 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 Ossatron, Evotron, Reflectron and dermaPACE will be regulated as medical device products.

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.

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 have this certification and will need to maintain it in order to have the potential to gain approval of a product candidate in Canada.

European Good Manufacturing Practices ("GMP")

In the European Union, the manufacture of medical devices is subject to good manufacturing practice, or 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 state and Federal law 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. Although we intend to structure our future business relationships with 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 health care 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.

A key component 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. While there are no specific codes for our wound care product candidates, there are existing codes that describe various wound care services and products used during the course of those services. It remains uncertain whether third party payers will determine that existing billing codes should be used to report procedures using our products. We expect to demonstrate through clinical evidence and economic studies that clinical outcomes achieved with our products are comparable or superior to other covered therapies. For non-wound care indications of our product candidates, we expect that a new billing code will likely be required, and we will seek a new code as part of our efforts to commercialize such product candidates.

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.

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, 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 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 1% of operating profit, for sales of FDA-approved wound care products in excess of $500,000 of earnings before interest and taxes. During the period beginning September 2005 through December 2009, we have paid $300,000 under the agreement.

Employees

As of December 31, 2009, we had a total of 25 employees in the United States. Of these 25 full-time employees, 11 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.

We have invested and continue to invest a significant portion of our time and resources in developing and testing our PACE™ product candidates, with current emphasis on dermaPACE™. 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 significant expenses for clinical trials. As of December 31, 2009, we had an accumulated deficit of $38.7 million. In June 2009, we sold our Versatron® veterinary product line. This transaction enabled us to focus our expertise and future development efforts on the development of our PACE™ technology in wound care, orthopedic/spine, plastic/cosmetic and cardiac conditions. 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.

Current economic conditions could adversely affect our operations.

According to the National Bureau of Economic Research, the United States economy has been in a recession since December 2007. This economic downturn and the instability of the credit and equity markets have made the business climate more volatile and more costly. Consequently, our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. A more radical economic downturn or increase in our expenses will likely make it more difficult for us to seek additional financing, and may force us to accept less than attractive rates or terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business strategy, financial performance and stock price, and could require us to delay or abandon product development plans or plans to acquire additional technology.

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;
- 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 with, 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 and technology licenses 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 prescribe 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, our ability to deliver our products to market will likely be impeded.

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 revenues.

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

As a small company with 25 employees, our success depends on the continuing contributions of our management team and scientific personnel, and on maintaining relationships with the network of medical and academic centers that conduct our clinical trials. We depend on the services of our key scientific employees and principal members of our management team. 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.

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 and 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, 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 and 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 and 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. 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 and 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.

Regulatory Risks

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

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.

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.

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.

In March 2010, the Congress passed sweeping healthcare reform in the Patient Protection and Affordable Care Act. We have not been able to assess the impact of this legislation on the Company, but it could result in new taxes on revenues for medical device companies and impact the utilization and reimbursement of our product candidates In addition, from time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of our products and product candidates. 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.

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 more 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.

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.

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 in which our approved products may be sold 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 and results of operations.

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 any one of our studies 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 our product candidates.

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 operating results.

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

We conduct research and development and some 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 Our Common Stock

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") and NightWatch Capital LLC ("NightWatch") for the ongoing financial support necessary to operate our business. Neither Prides nor NightWatch 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 for financing. 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.

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 stockholder 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 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.

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

As of March 15, 2010, Prides owned 67.3% of our outstanding common stock and NightWatch owned 16.4% of our outstanding common stock on a fully diluted basis. In addition, certain of our directors were appointed by Prides and NightWatch to serve on our board of directors. For as long as Prides and NightWatch 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 stockholders on other matters. For as long as they own a significant percentage of our outstanding stock, even if less than a majority, Prides and NightWatch 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 stockholders, including mergers, consolidations, sales or dispositions of assets, reductions in share capital, other business combinations and amendments to our articles of incorporation. Prides and NightWatch 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 action that might be favorable to them, but not favorable to us or our other stockholders. Also, if either Prides or NightWatch 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 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;
- 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 requirements of Rule 15g-9 under the Securities Exchange Act of 1934, as amended. 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 voluntarily implemented various corporate governance measures, in the absence of which, shareholders may have more limited protections against interested director transactions, conflicts of interest and similar matters.

Recent Federal legislation, including the Sarbanes-Oxley Act of 2002, has resulted in the adoption of various corporate governance measures designed to promote the integrity of corporate management and the securities markets. Some of these measures have been adopted in response to legal requirements and others have been adopted by companies in response to the requirements of national securities exchanges, such as the New York Stock Exchange and the NASDAQ Stock Market. Among the corporate governance measures that are required under the rules of the national securities exchanges are those that address board of directors' independence, audit committee oversight and the adoption of a code of ethics. While we intend to adopt certain corporate governance measures, such as a code of ethics and an established audit committee, we presently only have one independent director. It is possible that if we were to have more independent directors on our board of directors, shareholders would benefit from somewhat greater assurances that internal corporate decisions were being made by disinterested directors and that policies had been implemented to define responsible conduct. For example, in the absence of a compensation committee comprised of at least a majority of independent directors, decisions concerning matters such as compensation packages to our executive officers may be made by our directors who have an interest in the outcome of the matters being decided. Prospective investors should bear in mind our current lack of both corporate governance measures and a majority of independent directors in formulating their investment decisions.

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 July 31, 2011.

Item 3. LEGAL PROCEEDINGS

Other than legal proceedings 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 several material pending legal proceedings relating to our patents. For information regarding these legal proceedings, please see "Intellectual Property — Patents" above.

HealthTronics, 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. The plaintiff is seeking greater than $3 million. HealthTronics 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. [Removed and Reserved]

PART II

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

Market Information

The Company's stock is quoted on the OTCBB under the symbol "SNWV." Prior to the Merger, the Company's common stock was quoted on the OTCBB under the symbol "RBME;" however, there was no established public trading market for the common stock. From our initial quotation in October 2008 until the Merger, no trades occurred.

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, since our common stock commenced public trading after the Merger on September 25, 2009. The quotations reflect inter-dealer prices, without mark-up, mark-down or commissions, and may not represent actual transactions:

	Price Range	
	High	Low
2009		
First Quarter	N/A	N/A
Second Quarter	N/A	N/A
Third Quarter	$ 5.25	$ 5.25
Fourth Quarter	$ 6.00	$ 4.00

Holders of the Common Stock

As of December 31, 2009, there were approximately 63 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 (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflecting in column (a)) (c)
Equity compensation plans approved by security holders	—	—	—
Equity compensation plans not approved by security holders	1,979,546	$ 3.70	363,080
Total	1,979,546	$ 3.70	363,080

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

Overview

We are an emerging medical technology company focused on the development and commercialization of noninvasive, biological response activating devices in the regenerative medicine area 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 PACE 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 and Evotron® devices in Europe. Our lead product candidate 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.

With the divestiture of our worldwide Versatron® veterinary product line in June 2009, we are now entirely focused on developing our PACE technology to stimulate healing in:

- wound conditions, including diabetic foot ulcers, pressure sores, burns and other skin eruption conditions;
- orthopedic/spine applications, such as speeding the healing of fractures (including non-union 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 procedures for removing plaque due to atherosclerosis and improving heart muscle performance.

Recent Developments

We are enrolling patients for our first IDE wound care clinical study focused on the healing of diabetic foot ulcers utilizing our lead product candidate, dermaPACE. We believe our experience from preclinical research and the clinical use of our predecessor devices in Europe and Asia, as well as our Ossatron device in the United States for the last nine years, demonstrates the safety, clinical utility and efficacy of our product candidates. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications, as well as toward the development of next generation devices utilizing our PACE technology to maximize healing response and intervention.

We believe that those studies suggest that our platform technology will be effective in our target applications. If successful, we expect 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 non-invasive 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.

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 sale of our veterinary division in June 2009, and product sales. At December 31, 2009, the balance of cash and cash equivalents totaled $1.8 million.

We continue to incur research and development expenses for clinical trials and the development of products for additional indications. We expect that research and development expenses will continue to increase 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. In addition, we anticipate that our general and administrative expenses will continue to increase as 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, 2009, we had an accumulated deficit of $38.7 million. 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 few 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. In addition, given the sale of our veterinary division in 2009 and the discontinuation of the Ossatron mobile service business in 2008, we do not currently have an FDA approved product in commercialization in the United States.

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 as businesses and individuals suffer from the current economic downturn.

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 "Risk Factors."

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 revenue recognition, accrued expenses, fair valuation of inventory, fair valuation of stock related to stock-based compensation and income taxes. 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 discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any other future period.

While our significant accounting policies are more fully described in Note 1 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, 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. Fees from services performed are recognized when the procedure 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, and consists primarily of the purchase of component materials for assembly of finished products, less reserves for obsolescence.

Stock-based Compensation

During 2006, SANUWAVE, Inc.'s board of directors approved the adoption of the 2006 Stock Incentive Plan (the "Plan"). The Plan provides that stock options, other equity interests or equity-based incentives in SANUWAVE, Inc. may be granted to key personnel at an exercise price determined by SANUWAVE, Inc.'s board of directors, at the time the option is granted, taking into account the fair value of the common stock on the date of grant. The maximum term of any option granted pursuant to the Plan is ten years from the date of grant.

In accordance with ASC 718, *Compensation — Stock Compensation* (formerly included in 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 using the following weighted average assumptions amortized to expense over the options' vesting periods for the years ended December 31, 2009 and 2008, respectively: risk-free interest rate of 2.41% and 3.29%, expected dividend yield of 0% and 0%, volatility factor of the expected market price of our common stock of 65.0% and 46.3%, and weighted average expected life of the option of 6.0 and 6.0 years. 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. The risk-free rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of the grant.

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 carry-forwards, 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.

Effective January 1, 2007, we 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. The adoption of ASC 740 did not have a material effect on the Company.

Results of Operations for the Years ended December 31, 2009 and 2008

Disposal of Veterinary Division

On June 3, 2009, we sold our veterinary division for $3.5 million in cash to Pulse Veterinary Technologies, LLC. As a result, we recorded a net gain, before income taxes, of $2.5 million on the transaction. Under terms of the asset purchase agreement, we will continue to provide purchasing, production, shipping and warehousing services to Pulse Vet for a fee until April 30, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. The revenue for these transitional services is included in other income (expense). The income from discontinued operations, net of tax, was $0.3 million for the year ended December 31, 2009, as compared to $2.0 million for the same period in 2008.

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2009 were $0.7 million, compared to $1.0 million for the same period in 2008, a decrease of $0.3 million, or 37%. These revenues result primarily from sales of devices and applicators in Europe of our legacy Evotron® device for orthopedic conditions and our dermaPACE device for advanced wound care and decreased for the year ended December 31, 2009 compared to 2008 primarily because of declining sales of the legacy Evotron® device due to our focus on our resources in the United States with the elimination in 2009 of our European sales and marketing staff.

Cost of revenues for the year ended December 31, 2009 was $0.2 million, compared to $0.4 million for the same period in 2008. Gross profit as a percentage of revenues was 66% for the years ended December 31, 2009 and 2008. The continuity of the gross profit between 2009 and 2008 was primarily due to increasing sales in 2009 of the higher margin dermaPACE device applicator kits as a percentage of sales which is offset by increased costs of freight to and from Europe in 2009 due to the elimination in 2009 of our European office.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2009 were $3.4 million, compared to $3.7 million for the same period in 2008, a decrease of $0.3 million, or 8%. Research and development costs in 2008 included a one-time cost of $0.3 million for the development of RFID technology for the dermaPACE device.

We expect that research and development expenses to increase as a result of next generation technology development, the ongoing 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.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2009 were $5.0 million, compared to $7.8 million for the same period in 2008, a decrease of $2.8 million, or 36%. We closed our European office, effective April 2009. Expenses related to this office totaled $0.7 million for the year ended December 31, 2009, compared to $2.7 million for the same period in 2008. Excluding these costs, general and administrative expenses were $4.3 million for the year ended December 31, 2009, as compared to $5.1 million for the same period in 2008, a decrease of $0.8 million, or 16%.

General and administrative expenses include the non-cash compensation costs for stock compensation of $1.1 million for the year ended December 31, 2009, compared to $0.5 million for the same period in 2008, due to new grants of options, warrants and restricted stock to employees and directors of the Company in 2009. In addition, in 2009 the Company recorded legal, accounting and related expenses of $0.3 million in regard to the Merger. Excluding these costs and the costs related to the European office, general and administrative expenses were $2.9 million for the year ended December 31, 2009, as compared to $4.6 million for the same period in 2008, a decrease of $1.7 million, or 37%. The decrease is primarily due to reduced headcount and the related savings in wages, bonuses and benefit related expenses, and reduced legal expenses in 2009.

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

Depreciation and Amortization

Depreciation and amortization for the year ended December 31, 2009 was $0.7 million, compared to $0.6 million for the same period in 2008, an increase of $0.1 million, or 15%.

Other Income (Expense)

On June 3, 2009, we sold our veterinary division to Pulse Vet. Under terms of the asset purchase agreement, we will continue to provide purchasing, production, shipping and warehousing services to Pulse Vet for a fee until April 30, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. The revenue for these transitional services was $0.2 million for the year ended December 31, 2009.

Interest expense due to related parties for the year ended December 31, 2009 was $0.8 million, compared to $0.3 million for the same period in 2008, an increase of $0.5 million. The increase was due to interest on notes payable issued to Prides Capital Fund I, L.P., totaling $3.1 million, entered into between October 2008 and May 2009, and one note payable issued to NightWatch Capital Partners II, L.P., for $0.1 million, entered into in October 2008. The notes payable to related parties bear interest at 15% annually. Interest is paid quarterly in arrears, if elected by the holders of the notes payable. As of December 31, 2009, the holders of the notes payable had not elected to receive interest quarterly. All remaining unpaid accrued interest and principal is due September 30, 2011.

Provision for Income Taxes

At December 31, 2009, we had Federal net operating loss carryforwards of approximately $32.8 million 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. 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 Income (Loss)

Net loss for the year ended December 31, 2009 was $6.2 million, or $(0.54) per basic and diluted share, compared to net loss of $9.4 million, or $(0.85) per basic and diluted share, for the year ended December 31, 2008. This included a loss from continuing operations of $8.0 million, or $(0.70) per basic and diluted share, for the year ended December 31, 2009, compared to a loss from continuing operations of $11.4 million, or $(1.03) per basic and diluted share, for the year ended December 31, 2008. We anticipate that our operating losses will continue over the next few 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

We incurred a net loss of $6.2 million for the year ended December 31, 2009, which includes a loss from continuing operations of $8.0 million. We incurred a net loss of $9.4 million for the year ended December 31, 2008. These operating losses create an uncertainty about our ability to continue as a going concern. Management believes we will raise additional capital through public or private equity offerings, outstanding warrant exercises or other potential financing sources. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. We are economically dependent upon future capital contributions or financing to fund ongoing operations. On June 3, 2009, we sold our veterinary division for $3.5 million in cash to Pulse Vet. During the years ended December 31, 2009 and 2008, we obtained cash infusions totaling $2.1 million and $1.1 million, respectively, in the form of notes payable from related parties. The notes payable can be converted into additional shares of common stock, with all or any portion of the unpaid principal, at a conversion price of $2.92 per share. In addition, for the years ended December 31, 2009 and 2008, additional shares of stock were issued to stockholders for total cash proceeds of $1.8 million and $5.8 million, respectively.

At December 31, 2009, we had $1.8 million in cash and cash equivalents held in three financial institutions. Our excess cash reserves are invested in money market accounts.

We expect to devote substantial resources to continue our research and development efforts, including clinical trials. Clinical study costs are comprised of payments for work performed by contract research organizations, universities and hospitals. 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 may raise additional capital through public or private equity offerings, outstanding warrant exercises, debt financings, corporate collaborations or other means. We may attempt to raise additional capital due to 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 stockholders 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. 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. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our research, pre-clinical or clinical programs.

For the year ended December 31, 2009, net cash used by continuing operations for operating activities was $5.5 million, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by continuing operations for financing activities for the year ended December 31, 2009 was $3.7 million, which consisted primarily of the proceeds from issuance of notes payable to related parties of $2.1 million and the sale of common stock to accredited investors of $1.8 million, offset by the repurchase of common stock prior to the Merger of $0.2 million. Net cash provided by discontinued operations was $2.8 million for the year ended December 31, 2009, which includes $3.5 million from the sale of our veterinary division.

For the year ended December 31, 2008, net cash used by continuing operations for operating activities was $9.5 million, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash used by continuing operations for investing activities was $0.1 million for the year ended December 31, 2008 and included purchases of property and equipment for research and development. Net cash provided by continuing operations for financing activities for the year ended December 31, 2008 was $6.8 million, primarily consisting of $5.7 million in net proceeds from issuance of capital stock to related parties and $1.1 million in proceeds from the issuance of notes payable to related parties. Net cash provided by discontinued operations was $2.9 million for the year ended December 31, 2008.

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.

Comprehensive 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 comprehensive loss as defined by ASC 220 is the total of net 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 have 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 $8,075, 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 continues until July 31, 2010, and we have extended the lease until July 31, 2011.

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 contractual obligations under a supply agreement with Swisstronics Contract Manufacturing AG for the manufacture of our devices.

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, we entered into two promissory notes with HealthTronics for $2.0 million each. The promissory notes bear interest at 6% annually. Quarterly interest through June 30, 2010 is 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 promissory notes totaled $1.2 million and $0.9 million at December 31, 2009 and 2008, respectively.

During the period October 2008 through May, 2009 we issued notes payable to Prides Capital Fund I, L.P. for $3.1 million in total and one note payable to NightWatch Capital Partners II, L.P. for $0.1 million. The notes payable bear interest at 15% annually. Interest is paid quarterly in arrears if elected by the holders of the notes payable. As of December 31, 2009, the holders of the notes payable had not elected to receive interest quarterly. All remaining unpaid accrued interest and principal is due September 30, 2011. All or any portion of the unpaid principal can be converted into common stock with a conversion price of $2.92 per share. Accrued interest on the notes payable totaled $0.5 million and $20,251 at December 31, 2009 and 2008, respectively.

Recent Accounting Pronouncements

The FASB Accounting Standards Codification™

In June 2009, the Financial Accounting Standards Board ("FASB") issued SFAS No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles* ("SFAS No. 168"), which establishes the FASB Accounting Standards Codification ™ (the "Codification"). The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental United States generally accepted accounting principles. The Codification did not change United States generally accepted accounting principles but reorganizes the literature. All other accounting literature not included in the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009 and is effective for interim and annual periods ending after September 15, 2009. Subsequent changes to the Codification will be released through Accounting Standards Updates ("ASU"), which serve to update the Codification, provide background information about the guidance and provide the basis for conclusions on the changes in the Codification. The Company has conformed its consolidated financial statements and related notes to the new Codification for the year ended December 31, 2009.

In conjunction with the issuance of SFAS No. 168, the FASB issued ASU No. 2009-01 Topic 105, *Generally Accepted Accounting Principles* ("ASU No. 2009-01"). ASU No. 2009-01 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with United States generally accepted accounting principles. ASU No. 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of this ASU did not have a material impact on the Company's financial position or results of operation as of and for the year ended December 31, 2009.

Fair Value Measurements and Other-Than-Temporary Impairments

In April 2009, the FASB issued three Staff Positions ("FSP"): (1) ASC 320-10, *Investments - Debt and Equity Securities* (includes former FSP No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments)*. The ASC changes existing guidance for determining whether impairment of debt securities is other-than-temporary; (2) ASC 820-10, *Fair Value Measurements and Disclosures* (includes former FSP No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). This ASC, while emphasizing that the objective of fair value measurement described in ASC 820 (formerly SFAS No. 157, *Fair Value Measurements*) remains unchanged, provides additional guidance for determining whether market activity for a financial asset or liability has significantly decreased, as well as for identifying circumstances that indicate that transactions are not orderly; and (3) ASC 825-10, *Financial Instruments* (includes former FSP No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*). This ASC requires disclosures about fair values of financial instruments in all interim financial statements, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. These ASCs were effective for interim and annual periods ending after June 15, 2009. The Company adopted the ASCs effective January 1, 2009, and the adoption of did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2009.

Business Combinations

In April 2009, the FASB issued ASC 805-10, *Business Combinations* (includes former FSP No. FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*). This ASC amends and clarifies the provisions of ASC 805, formerly SFAS No. 141(R), *Business Combinations*, with respect to the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies associated with a business combination. The provisions of the ASC are effective, for the Company, for business combinations occurring after January 1, 2009. The adoption of the ASC did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2009.

Subsequent Events

In May 2009, the FASB issued ASC 855, *Subsequent Events* (formerly SFAS No. 165, *Subsequent Events*), which provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. This ASC distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. ASC 855 is effective for interim and annual periods ending after June 15, 2009. The Company has adopted ASC 855, and has evaluated subsequent events through the date the accompanying consolidated financial statements were issued.

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 are incorporated herein by reference to the consolidated financial statements beginning on Page F-1.

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

None.

Item 9A (T). CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These controls and procedures are designed to ensure that the required information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, 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 and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of December 31, 2009. 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, 2009.

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 affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's 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 and the Chief Financial Officer, evaluated the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework. Based on this evaluation, management, with the participation of the Chief Executive Officer and the Chief Financial Officer, concluded that, as of December 31, 2009, the Company's internal control over financial reporting was effective.

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	42	President, Chief Executive Officer and Director Officer
Barry J. Jenkins	47	Chief Financial Officer
Thomas H. Robinson	51	Director
Kevin A. Richardson, II	41	Director
John F. Nemelka	43	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 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 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. He was also the Chief Financial Officer of Snowden Pencer, Inc. from January of 2002 to November of 2004. Mr. Jenkins is a certified public accountant with 25 years of financial management experience and a cum laude graduate of Virginia Tech.

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 our board of directors experience based on his diverse experience with medical device companies both in providing executive search services to them as well as working for them in leadership and Director positions. Since 1998, Mr. Robinson has served as managing partner of the North American medical technology practice, which includes the medical device, hospital supply/distribution and medical software areas, of Spencer Stuart, Inc., a global executive search firm. Since 2002, Mr. Robinson has been a member of Spencer Stuart's board services practice, which assists corporations identifying and recruiting outside directors. From 1998 to 2000, Mr. Robinson headed Spencer Stuart's North American biotechnology specialty 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 also 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., an aesthetic medical laser company.

Kevin A. Richardson, II 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. 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 weight loss solutions company, and Pegasus Solutions, Inc., a travel technology company.

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 financial and operational 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 holding company, formerly KANA Software, Inc., a provider of customer service software solutions.

CODE OF CONDUCT AND ETHICS AND AUDIT COMMITTEE FINANCIAL EXPERT

It is our policy to conduct our affairs in accordance with all applicable laws, rules and regulations of the jurisdictions in which we do business. While we intend to adopt certain corporate governance measures, we have not established a formal code of ethics or an audit committee, as we presently have only one independent director.

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, 2009, 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 2009 and 2008

The following table provides certain information for the fiscal years ended December 31, 2009 and 2008 concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2009 and 2008.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)[2]	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Christopher M. Cashman	2009	$ 305,000	—	—	$1,463,957	—	—	$ 20,012	$1,788,969
Chief Executive Officer and President	2008	$ 305,000	—	—	$ 677,860	—	—	$ 18,101	$1,000,961
Barry J. Jenkins	2009	$ 222,600	—	—	$ 555,835	—	—	$ 19,149	$ 797,584
Chief Financial Officer	2008	$ 222,600	—	—	$ 327,316	—	—	$ 17,879	$ 567,795
Cornelius A. Hofman [1]	2009	—	—	—	—	—	—	—	—
Former Sole Officer and Director	2008	—	—	—	—	—	—	—	—

(1) Cornelius A. Hofman resigned as an officer and director, effective October 17, 2009, following the Merger.

(2) Includes health, dental and disability insurance premiums and employee 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 SANUWAVE, Inc. for a term commencing on December 19, 2005 and with no specific duration. Mr. Cashman is entitled to an annual base salary of $275,000. Effective January 1, 2010, Mr. Cashman is entitled to an annual base salary of $350,000, and effective January 1, 2011, he is 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 increase 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 SANUWAVE, Inc.'s budget and performance goals established for other management employees. Mr. Cashman is also entitled to participate in SANUWAVE, Inc.'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 will be paid by SANUWAVE, Inc. 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 vest and become 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 first supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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) December 19, 2011, and (ii) the date that SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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) December 19, 2011, and (ii) the date that SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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).

In addition, upon the execution of the first amendment to his employment agreement, 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 2009.

Gross-Ups. In the event that any payment made to Mr. Cashman under his employment agreement or under any other plan maintained by SANUWAVE, Inc. is subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, SANUWAVE, Inc. 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 SANUWAVE, Inc. at least 30 days advance written notice of any resignation. If Mr. Cashman is terminated by SANUWAVE, Inc. 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 SANUWAVE, Inc. If Mr. Cashman is terminated by SANUWAVE, Inc. 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 twelve months following the date of termination, and (2) continued coverage of him and his beneficiaries under SANUWAVE, Inc.'s health insurance programs for a period of up to twelve months.

Effective as of the first anniversary of the Merger, if Mr. Cashman is terminated by SANUWAVE, Inc. 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 SANUWAVE, Inc., (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. Effective as of the first anniversary of the Merger, Mr. Cashman's right to receive the above change of control termination benefits will no longer be 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 SANUWAVE, Inc. to a person (other than Prides or NightWatch) that will continue the business of SANUWAVE, Inc. in the future; (2) a merger or consolidation involving SANUWAVE, Inc. in which the voting securities of SANUWAVE, Inc. owned by the shareholders of SANUWAVE, Inc. 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 or NightWatch) is or becomes the beneficial owner, directly or indirectly, of more than 50% of the total voting power of the voting stock of SANUWAVE, Inc. and the representatives of Prides and NightWatch 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 SANUWAVE, Inc. for a term 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 SANUWAVE, Inc.'s budget and performance goals established for other management employees. Mr. Jenkins is also entitled to participate in SANUWAVE, Inc.'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 vest and become 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 option 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 SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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 adjusted 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 SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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 SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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 SANUWAVE, Inc. at least 30 days advance written notice of any resignation. If Mr. Jenkins is terminated by SANUWAVE, Inc. 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 SANUWAVE, Inc. If Mr. Jenkins is terminated by SANUWAVE, Inc. 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 SANUWAVE, Inc.'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"). The 2006 Plan sets aside 684,666 shares of common stock for grants to employees, directors and certain independent contractors, consultants and advisors. The terms of the options granted under the 2006 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 SANUWAVE, Inc. is terminated by SANUWAVE, Inc. for cause; (2) 60 days after the participant's death; or (3) 60 days after the termination of the participant's service with SANUWAVE, Inc. 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 SANUWAVE, Inc. The options vest as provided for in individual option agreements 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 SANUWAVE, Inc.'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 2006 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 plan.

On December 31, 2009, there were 363,080 shares of common stock available for grant under the 2006 Plan. No options were granted to the Company's executive officers during the 2009 fiscal year under the 2006 Plan. The 2006 Plan expires in October of 2016. The Company intends to assume and adopt the 2006 Plan.

Outstanding Equity Awards at 2009 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2009.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Christopher M. Cashman	723,600	—	—	$ 2.92	12/19/2015	—	—	—	—
	—	139,167	—	$2.92/$5.25	12/19/2015	—	—	—	—
	—	139,167	—	$2.92/$5.25	12/19/2015	—	—	—	—
	—	208,752	—	$2.92/$5.25	12/19/2015	—	—	—	—
Barry J. Jenkins	267,028	—	—	$ 2.92	10/24/2016	—	—	—	—
	—	—	—	—	—	29,663	$ 126,068	—	—
	—	89,009	—	$ 2.92	10/24/2016	—	—	—	—
	—	34,778	—	$2.92/$5.25	10/24/2016	—	—	—	—
	—	34,778	—	$2.92/$5.25	10/24/2016	—	—	—	—
	—	52,166	—	$2.92/$5.25	10/24/2016	—	—	—	—
Cornelius A. Hofman	—	—	—	—	—	—	—	—	—

Discussion of Director Compensation

SANUWAVE did not pay any director compensation during the fiscal years ended December 31, 2009 or 2008. The Company may begin to compensate its directors at some time in the future. During the year ended December 31, 2009, the Company issued options to purchase the Company's common stock at $2.92 per share to the non-employee directors as follows: options to purchase 15,000 shares to Thomas H. Robinson; options to purchase 5,000 shares to Kevin A. Richardson, II; and, options to purchase 5,000 shares to John F. Nemelka. The options were vested when granted and expire ten years after the date of 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 15, 2010, with respect to the beneficial ownership of the Company's outstanding common stock by (i) any holder of more than five percent, (ii) each of the Company's executive officers and directors, and (iii) the Company's directors and executive officers as a group.

Name of Beneficial Owner[1]	Number of Shares Beneficially Owned[2]	Percent of Shares Outstanding
Christopher M. Cashman[3]	1,061,673	8.0%
Barry J. Jenkins[4]	513,287	4.0%
Thomas H. Robinson	15,000	*
Kevin A. Richardson, II	5,000	*
John F. Nemelka	5,500	*
Prides Capital Fund I, LP[5]	9,797,763	67.3%
NightWatch Capital Partners II, LP[6]	2,090,187	16.4%
All directors and executive officers as a group (5 persons)	1,600,460	12.0%

* 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 15, 2010. 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 Securities Exchange Act of 1934, as amended, referred to in this report as the Exchange Act. Pursuant to the rules of the Securities and Exchange Commission, referred to in this report as the SEC, certain shares of our common stock that a beneficial owner has the right to acquire within 60 days pursuant to the exercise of stock options or warrants are deemed to be outstanding for the purpose of computing the percentage ownership of such owner, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

(3) Includes options to purchase up to 723,600 shares of common stock and warrants to purchase up to 8,816 shares of common stock.

(4) Includes options to purchase up to 356,037 shares of common stock and warrants to purchase up to 3,508 shares of common stock.

(5) Includes warrants to purchase up to 775,726 shares of common stock and notes convertible into 1,264,771 shares of common stock. The principal business address of Prides Capital Fund I, LP is 200 State Street, 13th floor, Boston, MA 02109.

(6) Includes warrants to purchase up to 187,522 shares of common stock and notes convertible into 31,923 shares of common stock. The principal business address of NightWatch Capital Partners II, LP is 5314 River Run Drive, Suite 350, Provo, Utah 84604.

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

Other than as described below, for the fiscal year ended December 31, 2009, there were no transactions with related persons required to be disclosed in this report. During January 2009 through May 2009, SANUWAVE, Inc. issued notes payable, totaling $2.1 million, to Prides Capital Fund I, L.P., a shareholder of the Company. Kevin A. Richardson, II, one of our directors and a director of SANUWAVE, Inc., serves as a managing partner of Prides Capital, LLC, an affiliate of Prides Capital Fund I, L.P. As of December 31, 2009, no principal has been paid on the notes. The notes bear interest at 15% annually. Interest is paid quarterly in arrears if elected by the holders of the notes. As of December 31, 2009, the holders of the notes had not elected to receive interest quarterly. All remaining unpaid accrued interest and principal is due September 30, 2011.

Our board of directors has determined that Thomas H. Robinson qualifies as an independent director based on the NASDAQ Stock Market definition of "independent director."

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 for each of the last two fiscal years:

Fee Category	2009	2008
Audit fees	$ 92,000	$ 73,000
Tax fees	13,700	14,900
Total fees	$ 105,700	$ 87,900

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 of Forms 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.

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 Securities and Exchange Commission. 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.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. All financial statements

Consolidated financial statements filed as part of this report are listed under Item 8. "Financial Statements and Supplementary Data."

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 filed or incorporated by reference as part of this report.

SANUWAVE HEALTH, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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 sheets of

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

as of December 31, 2009 and 2008, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes 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 audits provide a reasonable basis for our opinion.

The Company is not required to have, nor were we engaged to perform an audit of internal controls over financial reporting. Our audit included consideration of internal controls 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 controls over financial reporting. Accordingly, we express no such 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, 2009 and 2008, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As shown in the consolidated financial statements, the Company incurred a net loss of approximately $6,153,000 and $9,409,000 during the years ended December 31, 2009 and 2008, respectively, and, as of those dates, had a working capital deficiency of approximately $187,000 and $418,000, respectively. As described more fully in Note (16) 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 the uncertainty.

/s/ HLB Gross Collins, P.C.

Atlanta, Georgia
March 8, 2010, except for Note 20, which is as of March 26, 2010

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2009 and 2008

	2009	2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 1,786,369	$ 543,626
Accounts receivable — trade, net of allowance for doubtful accounts of $20,762 in 2009 and $64,490 in 2008 (Note 1)	47,966	52,414
Inventory (Note 4)	592,589	684,750
Prepaid expenses	121,157	106,617
Due from Pulse Veterinary Technologies, LLC	127,878	—
Current assets related to discontinued operations (Note 3)	—	1,285,017
TOTAL CURRENT ASSETS	2,675,959	2,672,424
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 5)	88,706	279,791
OTHER ASSETS	32,169	81,017
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 6)	2,147,295	2,454,051
ASSETS HELD FOR SALE (Note 7)	922,956	—
NON-CURRENT ASSETS RELATED TO DISCONTINUED OPERATIONS (Notes 3 and 5)	—	1,011,734
TOTAL ASSETS	$ 5,867,085	$ 6,499,017
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$ 1,069,423	$ 975,811
Payroll and related	509,905	820,397
Accrued expenses (Note 8)	629,029	448,242
Liabilities related to discontinued operations (Note 3)	655,061	845,593
TOTAL CURRENT LIABILITIES	2,863,418	3,090,043
NOTES PAYABLE, RELATED PARTIES (Note 11)	8,887,981	6,006,815
TOTAL LIABILITIES	11,751,399	9,096,858
COMMITMENTS AND CONTINGENCIES (Note 14)	—	—
GOING CONCERN (Note 16)	—	—
STOCKHOLDERS' EQUITY (DEFICIT)		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized (Note 12)	—	2,833
COMMON STOCK, par value $0.001, 50,000,000 shares authorized	12,510	89
ADDITIONAL PAID-IN CAPITAL	32,741,593	30,103,124
ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	21,864	(196,646)
RETAINED DEFICIT	(38,660,281)	(32,507,241)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(5,884,314)	(2,597,841)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 5,867,085	$ 6,499,017

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, 2009 and 2008

	2009	2008
REVENUES	$ 660,725	$ 1,045,858
COST OF REVENUES	225,790	352,723
GROSS PROFIT	434,935	693,135
OPERATING EXPENSES		
Research and development	3,387,204	3,675,631
General and administrative	5,026,425	7,801,416
Depreciation	365,108	276,724
Amortization	306,756	306,756
TOTAL OPERATING EXPENSES	9,085,493	12,060,527
OPERATING LOSS	(8,650,558)	(11,367,392)
OTHER INCOME (EXPENSE)		
Gain on sale of assets	3,207	—
Transitional services provided to Pulse Veterinary Technologies, LLC	230,625	—
Interest expense	(739,847)	(306,843)
Loss on foreign currency exchange	(30,184)	(52,528)
TOTAL OTHER INCOME (EXPENSE)	(536,199)	(359,371)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(9,186,757)	(11,726,763)
INCOME TAX BENEFIT	1,203,172	333,718
LOSS FROM CONTINUING OPERATIONS	(7,983,585)	(11,393,045)
DISCONTINUED OPERATIONS (Note 3)		
Income from discontinued operations, net of tax of $226,234 in 2009 and $333,718 in 2008	344,200	1,984,127
Gain on sale of veterinary division, net of tax of $976,938 in 2009	1,486,345	—
INCOME FROM DISCONTINUED OPERATIONS	1,830,545	1,984,127
NET LOSS	(6,153,040)	(9,408,918)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	218,510	(270,655)
TOTAL COMPREHENSIVE LOSS	$ (5,934,530)	$ (9,679,573)
EARNINGS (LOSS) PER SHARE: (Note 10)		
Loss from continuing operations — basic	$ (0.70)	$ (1.03)
Loss from continuing operations — diluted	$ (0.70)	$ (1.03)
Income from discontinued operations — basic	$ 0.16	$ 0.18
Income from discontinued operations — diluted	$ 0.16	$ 0.18
Net loss — basic	$ (0.54)	$ (0.85)
Net loss — diluted	$ (0.54)	$ (0.85)
Weighted average shares outstanding — basic	11,405,490	11,009,657
Weighted average shares outstanding — diluted	11,405,490	11,009,657

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Years Ended December 31, 2009 and 2008

	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, 2007	226,500	$ 2,265	7,973	$ 80	$ 23,804,866	$(23,098,323)	$ 74,009	$ 782,897
Shares issued for cash	56,750	568	890	9	5,763,473	—	—	5,764,050
Net loss	—	—	—	—	—	(9,408,918)	—	(9,408,918)
Stock-based compensation	—	—	—	—	534,785	—	—	534,785
Foreign currency translation adjustment	—	—	—	—	—	—	(270,655)	(270,655)
Balances as of December 31, 2008	283,250	2,833	8,863	89	30,103,124	(32,507,241)	(196,646)	(2,597,841)
Shares issued for cash	—	—	18,198	182	1,819,662	—	—	1,819,844
Recapitalization pursuant to Merger	(283,250)	(2,833)	12,079,566	11,836	(9,003)	—	—	—
Shares purchased	—	—	—	—	(180,000)	—	—	(180,000)
Payment of development period liabilities	—	—	—	—	(69,915)	—	—	(69,915)
Net loss	—	—	—	—	—	(6,153,040)	—	(6,153,040)
Stock-based compensation	—	—	403,030	403	1,077,725	—	—	1,078,128
Foreign currency translation adjustment	—	—	—	—	—	—	218,510	218,510
Balances as of December 31, 2009	—	$ —	12,509,657	$ 12,510	$ 32,741,593	$(38,660,281)	$ 21,864	$(5,884,314)

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, 2009 and 2008

	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss from continuing operations	$ (7,983,585)	$(11,393,045)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization	306,756	306,756
Accrued interest	756,166	307,015
Depreciation	365,108	276,724
Change in allowance for doubtful accounts	(43,728)	(31,861)
Gain on sale of property and equipment	(3,207)	—
Stock-based compensation	1,078,128	534,785
Changes in assets — (increase)/decrease		
Accounts receivable — trade	48,176	89,851
Inventory	92,161	7,107
Prepaid expenses	(14,540)	222,352
Due from Pulse Veterinary Technologies, LLC	(127,878)	—
Other assets	48,848	60,752
Changes in liabilities — increase/(decrease)		
Accounts payable	93,612	(83,646)
Payroll and related	(310,492)	185,275
Accrued expenses	180,787	(21,599)
NET CASH USED BY CONTINUING OPERATIONS	(5,513,688)	(9,539,534)
NET CASH PROVIDED (USED) BY DISCONTINUED OPERATIONS	(758,244)	2,530,132
NET CASH USED BY OPERATING ACTIVITIES	(6,271,932)	(7,009,402)
CASH FLOWS FROM INVESTING ACTIVITIES		
Continuing operations		
Proceeds from sale of property and equipment	9,827	—
Purchase of property and equipment	(10,363)	(116,962)
NET CASH USED BY CONTINUING OPERATIONS	(536)	(116,962)
NET CASH PROVIDED BY DISCONTINUED OPERATIONS	3,601,772	408,562
NET CASH PROVIDED BY INVESTING ACTIVITIES	3,601,236	291,600
CASH FLOWS FROM FINANCING ACTIVITIES		
Continuing operations		
Proceeds from notes payable, related parties	2,125,000	1,075,000
Proceeds from sale of capital stock	1,819,844	5,764,050
Repurchase of common stock	(180,000)	—
Payment of development period liabilities	(69,915)	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,694,929	6,839,050
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS	218,510	(270,655)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,242,743	(149,407)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	543,626	693,033
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 1,786,369	$ 543,626

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

(1) Summary of significant accounting policies

Description of the business — SANUWAVE Health, Inc. and subsidiaries (the "Company") is a global medical technology company focused on the development and utilization of Pulsed Acoustic Cellular Expression (PACE™) technology for advanced wound care, orthopedic/spine, plastic/cosmetic, and cardiac conditions. Headquartered in Alpharetta, Georgia, the Company designs, manufactures, markets and services the Company's products worldwide.

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 shown as a separate component of accumulated other comprehensive income (loss) in the consolidated statements of stockholders' equity.

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

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

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.

Concentration of credit risk — 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. The Company maintains its cash in bank accounts which may exceed federally insured limits. The Company does not believe it is exposed to any significant credit risk in such accounts.

(1) Summary of significant accounting policies (continued)

Accounts receivable — Accounts receivable are stated at the amount management expects to collect from outstanding balances. Management provides for probable uncollectible amounts through a charge to earnings based on its assessment of the current status of individual accounts. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the valuation allowance. Receivables are considered past due on average if greater than 30 days old. The following is a summary of accounts receivable allowances:

	2009	2008
Balance at beginning of year	$ 64,490	$ 90,353
Less: reserve adjustments	(44,324)	(28,191)
Less: write-offs	—	(3,226)
Add: foreign currency translation	596	5,554
Balance at end of year	$ 20,762	$ 64,490

Inventory — Inventory consists of finished medical equipment and parts and is stated at the lower of cost or market. Cost has been determined on a weighted average basis. Market is based upon realizable value less allowance for selling and distribution expenses.

Depreciation of property and equipment — The straight-line method of depreciation is used for computing depreciation on all 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.

Impairment of long-lived assets — The Company reviews long-lived assets, other than goodwill and other intangible assets with indefinite lives, 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.

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

(1) Summary of significant accounting policies (continued)

Fair value of financial instruments — The book values of trade accounts receivable, trade accounts payable, and other financial instruments approximate their fair values, principally because of the short-term maturities of these instruments. The fair value of the Company's long-term debt is estimated based on current rates offered to the Company for debt of similar terms and maturities.

Revenue recognition — Sales of medical devices, including related applicators and applicator kits, are recognized when shipped to the customer. 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.

Deferred 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, 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.

Effective January 1, 2007, the Company 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. The adoption of ASC 740 did not have a material effect on the Company.

Earnings (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 (Note 10).

(1) Summary of significant accounting policies (continued)

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. Examples of items to be included in comprehensive income (loss), which are excluded from net income (loss), include foreign currency translation adjustments and unrealized gains and losses on available-for-sale securities.

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 four years) using the straight-line method.

Research and development costs — Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to 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.

Discontinued operations -The Company accounts for long-lived assets in accordance with the provisions of ASC 360, *Impairment or Disposal of Long-Lived Assets* (formerly SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets). ASC 360 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. ASC 360 requires companies to separately report discontinued operations and extends that reporting to a component of an entity that either has been disposed of (by sale, abandonment, or in a distribution to owners) or is classified as held for sale. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

On October 31, 2008, the Company discontinued the Ossatron® mobile service business and sold certain assets to a minority shareholder of the Company.

On June 3, 2009, the Company sold the net assets and liabilities of the veterinary business.

(1) Summary of significant accounting policies (continued)

As required by ASC 360, the results of operations from these businesses have been reported as discontinued operations in the consolidated statements of operations and comprehensive loss. All of the assets and liabilities related to these discontinued operations have been reclassified to current assets, non-current assets, and current liabilities related to discontinued operations, as applicable.

The results of operations for these businesses allocated to discontinued operations were those results the Company believes will be eliminated from the ongoing operations of the entity as a result of the disposal transactions. The Company identified such results via a line item review of the consolidated statements of operations and comprehensive loss. The income tax rate used for the tax effect of the discontinued operations is based on the effective tax rate for the Company.

Recent pronouncements — In June 2009, the Financial Accounting Standards Board ("FASB") issued SFAS No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles* ("SFAS No. 168"), which establishes the FASB Accounting Standards Codification™ (the "Codification"). The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental United States generally accepted accounting principles. The Codification did not change United States generally accepted accounting principles but reorganizes the literature. All other accounting literature not included in the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009, and is effective for interim and annual periods ending after September 15, 2009. Subsequent changes to the Codification will be released through Accounting Standards Updates ("ASU"), which serve to update the Codification, provide background information about the guidance and provide the basis for conclusions on the changes in the Codification. The Company has conformed its consolidated financial statements and related notes to the new Codification for the year ended December 31, 2009.

In conjunction with the issuance of SFAS No. 168, the FASB issued ASU No. 2009-01 Topic 105, *Generally Accepted Accounting Principles* ("ASU No. 2009-01"). ASU No. 2009-01 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with United States generally accepted accounting principles. ASU No. 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of this ASU did not have a material impact on the Company's financial position or results of operation as of and for the year ended December 31, 2009.

(1) Summary of significant accounting policies (continued)

In April 2009, the FASB issued three Staff Positions ("FSP"): (1) ASC 320-10, *Investments — Debt and Equity Securities* (includes former FSP No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments)*. The ASC changes existing guidance for determining whether impairment of debt securities is other-than-temporary; (2) ASC 820-10, *Fair Value Measurements and Disclosures* (includes former FSP No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). This ASC, while emphasizing that the objective of fair value measurement described in ASC 820 (formerly SFAS No. 157, *Fair Value Measurements*) remains unchanged, provides additional guidance for determining whether market activity for a financial asset or liability has significantly decreased, as well as for identifying circumstances that indicate that transactions are not orderly; and (3) ASC 825-10, *Financial Instruments* (includes former FSP No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*). This ASC requires disclosures about fair values of financial instruments in all interim financial statements, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. These ASCs were effective for interim and annual periods ending after June 15, 2009. The Company adopted the ASCs effective January 1, 2009, and the adoption of did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2009.

In April 2009, the FASB issued ASC 805-10, *Business Combinations* (includes former FSP No. FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*). This ASC amends and clarifies the provisions of ASC 805, formerly SFAS No. 141(R), *Business Combinations*, with respect to the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies associated with a business combination. The provisions of the ASC are effective, for the Company, for business combinations occurring after January 1, 2009. The adoption of the ASC did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2009.

In May 2009, the FASB issued ASC 855, *Subsequent Events* (formerly SFAS No. 165, *Subsequent Events*), which provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. This ASC distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. ASC 855 is effective for interim and annual periods ending after June 15, 2009. The Company has adopted ASC 855.

Reclassifications — Certain accounts in the prior-year consolidated financial statements have been reclassified for comparative purposes to conform with the presentation in the current-year consolidated financial statements.

(2) Reverse merger transaction

On September 25, 2009, the Company (formerly named Rub Music Enterprises, Inc.) and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of the Company (the "Merger Sub"), entered into a reverse merger agreement (the "Merger Agreement") with SANUWAVE, Inc. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, Inc., with SANUWAVE, Inc. as the surviving entity (the "Merger"). In connection with the Merger, the Company acquired 100% of the outstanding capital stock of SANUWAVE, Inc. and the stockholders of SANUWAVE, Inc. received 11,009,657 shares of the Company's common stock, warrants to purchase 1,106,627 shares of the Company's common stock at $4.00 per share, and warrants to purchase an additional 1,106,627 shares of the Company's common stock at $8.00 per share. In addition, in connection with the Merger, certain stockholders of the Company agreed to cancel all of their shares of common stock of the Company, except for 1,500,000 shares of common stock, for an aggregate price of $180,000 (the "Share Repurchase"). At the time of the Merger, the Company had 1,500,000 warrants outstanding to purchase the Company's common stock at $4.00 per share.

As a result of the Merger and Share Repurchase, the stockholders of SANUWAVE, Inc. control approximately 88% of the Company's outstanding common stock, holding 11,009,657 of the 12,509,657 outstanding shares, and SANUWAVE, Inc. is considered the accounting acquirer in this Merger. The Company was a "shell company" as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") immediately prior to the Merger. The Merger caused the Company to cease being a shell company as it no longer had nominal operations.

The Merger has been accounted for in the accompanying consolidated financial statements as if it occurred on January 1, 2008.

(3) Discontinued operations

On October 31, 2008, the Company discontinued its Ossatron® mobile service business. The Company sold certain assets for a total cash consideration of $400,000 to a minority shareholder of the Company and recorded a gain of approximately $106,000.

On June 3, 2009, the Company sold its veterinary business for a total cash consideration of $3,500,000. As a result of the sale, the Company recorded a gain, before income taxes, of $2,463,283.

Accordingly, the Company's consolidated financial statements have been prepared with the net assets, results of operations, and cash flows of these businesses displayed separately as "discontinued operations."

(3) Discontinued operations (continued)

The operating results of the discontinued operations are summarized as follows for the years ended December 31, 2009 and 2008:

	2009	2008
Revenues	$ 1,458,107	$ 5,779,988
Cost of revenues	372,547	1,067,468
Gross profit	1,085,560	4,712,520
Operating expenses		
Depreciation expense	3,843	1,176,931
Other operating expenses	506,789	1,413,856
Total operating expenses	510,632	2,590,787
Operating income	574,928	2,121,733
Other income/(expense)		
Interest income	74	180
Gain/(loss) on sale of assets	(7,030)	32,080
Other expense	—	(74,048)
Gain on foreign currency exchange	2,462	237,900
Total other income/(expense)	(4,494)	196,112
Income from discontinued operations before income taxes	570,434	2,317,845
Income tax expense	226,234	333,718
Income from discontinued operations, net of income tax	$ 344,200	$ 1,984,127

(3) Discontinued operations (continued)

As of December 31, 2009 and 2008, the Company's assets and liabilities related to discontinued operations were as follows:

	2009	2008
Cash	$ —	$ 127,001
Accounts receivable — trade, net	—	581,200
Inventory	—	558,543
Prepaid expenses and other assets	—	18,273
Total current assets	—	1,285,017
Property and equipment, net	—	1,011,734
Total assets	—	2,296,751
Accounts payable and accrued expenses	(655,061)	(845,593)
Net assets (liabilities) of discontinued operations	$ (655,061)	$ 1,451,158

(4) Inventory

Inventory consists of the following at December 31, 2009 and 2008:

	2009	2008
Inventory — finished goods	$ 667,998	$ 644,725
Inventory — parts	108,068	218,044
	776,066	862,769
Provision for losses and obsolescence	(183,477)	(178,019)
Net inventory	$ 592,589	$ 684,750

(4) Inventory (continued)

Inventory related to discontinued operations (Note 3) consists of the following at December 31, 2009 and 2008:

	2009	2008
Inventory — finished goods	$ —	$ 258,035
Inventory — parts	—	300,508
	—	558,543
Provision for losses and obsolescence	—	—
Net inventory	$ —	$ 558,543

(5) Property and equipment

Property and equipment consists of the following at December 31, 2009 and 2008:

	2009	2008
Machines and equipment	$ 199,520	$ 204,711
Office and computer equipment	311,791	353,098
Leasehold improvements	67,421	91,590
Furniture and fixtures	24,613	34,915
Vehicles	38,897	—
Software	40,233	40,233
Other assets	4,585	21,688
Total	687,060	746,235
Accumulated depreciation	(598,354)	(466,444)
Net property and equipment	$ 88,706	$ 279,791

The aggregate depreciation charged to operations was $194,828 and $276,724 for the years ended December 31, 2009 and 2008, respectively. The depreciation policies followed by the Company are described in Note (1).

(5) Property and equipment (continued)

Property and equipment related to discontinued operations (Note 3) consists of the following at December 31, 2009 and 2008:

	2009	2008
Ossatron® devices	$ —	$ 4,837,165
Vehicles	—	376,511
Other assets	—	24,464
Total	—	5,238,140
Accumulated depreciation	—	(4,226,406)
Net property and equipment	$ —	$ 1,011,734

The aggregate depreciation charged to discontinued operations was $3,843 and $1,176,931 for the years ended December 31, 2009 and 2008, respectively.

(6) Intangible assets

Intangible assets consist of the following at December 31, 2009 and 2008:

	2009	2008
Patents, at cost	$ 3,502,135	$ 3,502,135
Less accumulated amortization	(1,354,840)	(1,048,084)
Net intangible assets	$ 2,147,295	$ 2,454,051

The aggregate amortization charged to amortization expense was $306,756 for each of the years ended December 31, 2009 and 2008. The amortization policies followed by the Company are described in Note (1).

(6) Intangible assets (continued)

Amortization expense for the future years is summarized as follows:

Years ending December 31,	Amount
2010	$ 306,756
2011	306,756
2012	306,756
2013	306,756
2014	306,756
2015 and thereafter	613,515
Total	$ 2,147,295

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

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

(7) Assets held for sale

On October 31, 2008, the Company discontinued its Ossatron® mobile service business and accordingly displayed the related assets of this business as "discontinued operations." In accordance with FASB ASC 205-20, *Presentation of Financial Statements — Discontinued Operations,* a quarterly review of the discontinued assets was performed to determine if they should continue to be recorded as "discontinued operations." As of October 1, 2009, management determined that the Ossatron® device fixed assets and related parts inventory were not likely to be sold within the next twelve months. Therefore, the Ossatron® device fixed assets and related parts inventory were reclassed to continuing operations and depreciation on the Ossatron® device fixed assets was restarted at October 1, 2009. Assets held for sale consist of the following at December 31, 2009 and 2008:

	2009	2008
Ossatron® devices	$ 4,837,165	$ —
Accumulated depreciation	(4,082,474)	—
Net property and equipment	754,691	—
Inventory Ossatron® device parts	210,169	—
Provision for losses and obsolescence	(41,904)	—
Net inventory	168,265	—
Total assets held for sale	$ 922,956	$ —

The aggregate depreciation charged to operations was $170,280 for the year ended December 31, 2009. There was no depreciation expense charged to operations for the year ended December 31, 2008.

(8) Accrued expenses

Accrued expenses consist of the following at December 31, 2009 and 2008:

	2009	2008
Accrued legal professional fees	$ 249,418	$ 22,000
Accrued clinical site payments	192,023	195,773
Accrued audit and tax preparation	77,771	81,160
Accrued other	109,817	149,309
	$ 629,029	$ 448,242

(9) Income taxes

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

The income tax provision (benefit) consists of the following at December 31, 2009 and 2008:

	2009	2008
Current:		
Federal	$ —	$ —
State	—	—
	—	—
Deferred:		
Federal	(2,193,248)	(2,770,299)
State	(240,974)	(304,374)
Foreign	61,056	(194,144)
Change in valuation allowance	2,373,166	3,268,817
	$ —	$ —

(9) Income taxes (continued)

The tax effects of temporary differences that give rise to the deferred tax assets (liabilities) at December 31, 2009 and 2008, are as follows:

	2009	2008
Deferred tax assets:		
Net operating loss carryforward	$ 12,359,566	$ 10,522,823
Net operating loss carryforward — foreign	220,983	282,039
Excess of tax basis over book value of intangible assets	405,628	401,600
Stock-based compensation	744,466	337,628
Accrued bonus	188,678	—
Capitalized equity costs	75,471	—
Other	—	21,201
Valuation allowance	(13,682,181)	(11,247,959)
Valuation allowance — foreign	(220,983)	(282,039)
Total deferred tax assets	91,628	35,293
Deferred tax liabilities:		
Excess of book value over tax basis of property and equipment	91,628	35,293
Deferred tax, net	$ —	$ —

The difference between the amount of reported income tax benefit and the tax benefit determined by applying the federal statutory tax rate of 35% to the pre-tax income from continuing operations is attributable primarily to the increase in the valuation allowance of $2,373,166 and $3,268,817 for 2009 and 2008, respectively. The schedule of federal net operating loss carryforwards at December 31, 2009, will expire as follows:

Years ending December 31,	Amount
2025	$ 1,376,740
2026	9,428,700
2027	10,291,249
2028	6,788,977
2029	4,867,401
Total	$ 32,753,067

(10) Earnings (loss) per share

The following table sets forth the computation of basic and diluted earnings per share pursuant to ASC 260.

	2009	2008
Numerator:		
Loss from continuing operations	$ (7,983,585)	$(11,393,045)
Income from discontinued operations	$ 1,830,545	$ 1,984,127
Net loss	$ (6,153,040)	$ (9,408,918)
Denominator:		
Denominator for basic earnings (loss) per share — weighted average shares outstanding during the year	11,405,490	11,009,657
Effect of dilutive securities:		
Notes payable, related parties	—	—
Warrants	—	—
Stock options	—	—
Denominator for diluted earnings (loss) per share — adjusted weighted average shares and assumed conversions	11,405,490	11,009,657
Loss from continuing operations per share — basic	$ (0.70)	$ (1.03)
Loss from continuing operations per share — diluted	$ (0.70)	$ (1.03)
Income from discontinued operations per share — basic	$ 0.16	$ 0.18
Income from discontinued operations per share — diluted	$ 0.16	$ 0.18
Net loss per share — basic	$ (0.54)	$ (0.85)
Net loss per share — diluted	$ (0.54)	$ (0.85)

As a result of the net loss for the years ended December 31, 2009 and 2008, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive common shares totaled 3,523,115 shares and 636,313 shares for the years ended December 31, 2009 and 2008, respectively.

(11) Notes payable, related parties

The notes payable consists of the following at December 31, 2009 and 2008:

	2009	2008
Notes payable, unsecured, bearing interest at 6% to HealthTronics, Inc. a shareholder of the Company. The notes were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. Quarterly interest through June 30, 2010, is 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 totaled $1,215,253 and $911,564 at December 31, 2009 and December 31, 2008, respectively.	$ 5,215,253	$ 4,911,564
Notes payable, unsecured, bearing interest at 15% to Prides Capital Fund I, LP and NightWatch Capital Partners II, LP, shareholders of the Company. Quarterly interest through December 31, 2009, is accrued and added to the principal balance. Interest is paid quarterly in arrears if elected by the holder. As of December 31, 2009, the holder has not elected to have interest paid. All remaining unpaid accrued interest and principal is due September 30, 2011. Accrued interest totaled $472,728 and $20,251 at December 31, 2009 and December 31, 2008, respectively. All or any portion of the unpaid principal can be converted into common stock with a conversion price of $2.92 per share.	3,672,728	1,095,251
Total	8,887,981	6,006,815
Less current portion	—	—
Non-current portion	$ 8,887,981	$ 6,006,815

(11) Notes payable, related parties (continued)

The notes payable to Prides Capital Fund I, LP and NightWatch Capital Partners II, LP contain a contingent put reflected in the contractual rights of default. Upon the occurrence of any default, as defined in the note agreements, the entire unpaid principal and accrued interest on the note will become automatically due and payable. Under FASB Codification ASC 815, the risks of equity are inconsistent with the risks of the debt host and, therefore, embedded put derivative such as these require bifurcation and separate classification at fair value when material. The value of the contingent put was determined to be deminimus in value and as such, was considered immaterial. The Company will continue to assess this element of the contract and if material, the Company will record the contingent put as a derivative liability and charge against income changes in fair value at each reporting period.

Maturities on long-term notes payable are as follows:

Years ending December 31,	Amount
2010	$ —
2011	3,672,728
2012	—
2013	—
2014	—
2015 and thereafter	5,215,253
Total	$ 8,887,981

Interest expense on notes payable, related parties totaled $756,166 and $307,015 for the years ended December 31, 2009 and 2008, respectively.

(12) Preferred stock

The Company's preferred stock may have such rights, preferences and designations and may be issued is such series as determined by the Board of Directors. No shares were issued and outstanding at December 31, 2009.

(13) Warrants

As of December 31, 2009, the Company had (1) Class A Warrants to purchase up to 1,106,627 shares of common stock outstanding, (2) Class B Warrants to purchase up to 1,106,627 shares of common stock outstanding, and (3) Class C Warrants to purchase up to 1,500,000 shares of common stock outstanding. The Class A Warrants and Class B Warrants expire on September 25, 2014, and the Class C Warrants expire on September 25, 2011. The Class A Warrants and Class C Warrants have an exercise price of $4.00 per share, and the Class B Warrants have an exercise price of $8.00 per share.

The exercise price and the number of shares covered by the Class A, B and C Warrants will be adjusted if the Company has a stock split, if there is a recapitalization of the Company's common stock, or if the Company consolidates with or merges into another corporation. The Class C Warrants may be redeemed by the Company if the closing price of the Company's common stock on the trading market is $5.00 per share or more, with 15,000 shares of average daily volume, for 20 consecutive trading days, or if the Company consummates a private offering of the Company's common stock. In both cases, the redemption price will be $0.01 per warrant.

(14) Commitments and contingencies

The Company leases office and warehouse space. Rent expense for the years ended December 31, 2009 and 2008, was $533,464 and $615,678, respectively. Minimum future lease payments under noncancellable operating leases consist of the following:

Years ending December 31,	Amount
2010	$ 301,808
2011	229,135
2012	190,945
Total	$ 721,888

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

(15) 401k plan

The Company sponsors a 401k plan that covers all employees who meet the eligibility requirements. The Company matches 50% of employee contributions up to 6% of their compensation. The Company contributed $69,602 and $78,717 to the plan for the years ended December 31, 2009 and 2008, respectively.

(16) Going concern

As shown in the accompanying consolidated financial statements, the Company incurred a net loss of $6,153,040 and $9,408,918 during the years ended December 31, 2009 and 2008, respectively. At December 31, 2009 and 2008, the Company's current liabilities exceeded its current assets by $187,459 and $417,619, respectively. Those factors create an uncertainty about the Company's ability to continue as a going concern. Management believes the Company will raise additional capital through public or private equity offerings, outstanding warrant exercise or other potential financing sources. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of recorded liability amounts that might be necessary if the Company is unable to continue as a going concern. The Company is economically dependent upon future capital contributions or financing to fund ongoing operations. On June 3, 2009, the Company sold the veterinary division for $3,500,000 in cash. During the years ended December 31, 2009 and 2008, the Company obtained cash infusions totaling $2,125,000 and $1,075,000, respectively, in the form of notes payable from related parties. The notes payable can be converted into additional shares of common stock, with all or any portion of the unpaid principal, at a conversion price of $2.92 per share. In addition, for the years ended December 31, 2009 and 2008, additional shares of stock were issued to stockholders for total cash proceeds of $1,819,844 and $5,764,050, respectively.

Subsequent to year end, the Company issued two promissory notes totaling $400,000 to two stockholders. The notes bear interest at 5% per annum and are due in June, 2010.

(17) Stock-based compensation

During 2006, SANUWAVE, Inc. approved the 2006 Stock Incentive Plan ("the Plan") and certain Nonstatutory Stock Option Agreements with key employees. The Nonstatutory Stock Option Agreements have terms substantially the same as the Plan. As of December 31, 2009, the Plan reserved approximately 684,666 shares of common stock for grant. The Plan permits granting of awards to selected employees and directors of SANUWAVE, Inc. in the form of restricted stock or options to purchase shares of common stock. Options granted may include Nonstatutory Options as well as Non-qualified Incentive Stock Options. The Plan is currently administered by the Board of Directors of SANUWAVE, Inc. The Plan gives broad powers to the Board of Directors of SANUWAVE, Inc. to administer and interpret the particular form and conditions of each option. The stock options granted were nonstatutory options which, under the Plan, vest equally over a four year period, and have a ten-year term. The options were granted to employees at an exercise price deemed to be the fair market value of the common stock on the date of the grant. It is SANUWAVE, Inc.'s policy to issue new stock certificates to satisfy stock option exercises. The Company intends to assume and adopt the Plan.

For the year ended December 31, 2009, SANUWAVE, Inc. awarded 403,030 shares of restricted stock to certain members of management. The restrictions on the stock will lapse at 25% per year from the employees first date of service with SANUWAVE, Inc. after the lock-up agreement expires on January 1, 2011, subject to other restrictions on the stock as more detailed in the restricted stock agreements.

(17) Stock-based compensation (continued)

For the year ended December 31, 2009, SANUWAVE, Inc. granted 163,745 options to employees at an exercise price of $2.92 per share and 55,000 options to employees at an exercise price of $5.25 per share.

For the year ended December 31, 2009, the Company granted certain employees Class A Warrants to purchase 6,344 shares of common stock and Class B Warrants to purchase 6,344 shares of common stock. The Class A Warrants have an exercise price of $4.00 per share and the Class B Warrants have an exercise price of $8.00 per share. These warrants were unexcercised and outstanding at December 31, 2009.

In addition, for the year ended December 31, 2009, SANUWAVE, Inc. 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 the employees the right to purchase 40,637 shares of common stock and the third supplemental option provided the employees the right to purchase 60,958 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) six years from the employee's first date of service, and (ii) the date that SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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) six years from the employee's first date of service, and (ii) the date that SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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) six years from the employee's first date of service, and (ii) the date that SANUWAVE, Inc. or its shareholders (A) enters into a transaction that establishes a value for SANUWAVE, Inc. on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for SANUWAVE, Inc. 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).

(17) Stock-based compensation (continued)

Using the Black-Scholes option pricing model, management has determined that the restricted stock, options and warrants granted during the years ended December 31, 2009 and 2008, have a weighted average fair value per share of $1.73 in 2009 and $1.42 in 2008, resulting in a total compensation cost of $2,464,655 and $1,481,207 in 2009 and 2008, respectively. Compensation cost will be recognized over the weighted average four year service period. For the years ended December 31, 2009 and 2008, the Company recognized $1,078,128 and $534,785, respectively, as compensation cost and recorded a related deferred tax benefit of $406,838 and $201,804, respectively. The remaining $2,673,579 of compensation cost will be recognized over the next four years as follows:

Years ending December 31,	Compensation Cost
2010	$ 1,768,558
2011	800,164
2012	69,189
2013	35,668
Total	$ 2,673,579

The assumptions used and the calculated fair value of options is as follows:

	2009	2008
Expected life in years	6.0	6.0
Risk free interest rate	2.41%	3.29%
Weighted average volatility	65.00%	46.30%
Expected dividend yield (1)	—	—

(1) The Company has not paid dividends on its common stock and does not expect to pay dividends on its common stock in the near future.

(17) Stock-based compensation (continued)

A summary of option activity as of December 31, 2009 and 2008, and the changes during the years ended December 31, 2009 and 2008, is presented as follows:

	Options	Weighted Average Exercise Price
Outstanding as of December 31, 2007	674,464	$ 3.53
Granted	1,334,437	$ 3.43
Exercised	(30,484)	$ 2.92
Forfeited or expired	(110,804)	$ 2.92
Outstanding as of December 31, 2008	1,867,613	$ 3.50
Granted	360,977	$ 4.19
Exercised	—	$ —
Forfeited or expired	(249,044)	$ 2.92
Outstanding as of December 31, 2009	1,979,546	$ 3.70
Exercisable	1,706,075	$ 3.20

The weighted average remaining contractual term for outstanding and exercisable stock options is 6.3 years as of December 31, 2009, and 7.2 years as of December 31, 2008.

A summary of the Company's nonvested options as of December 31, 2009 and 2008, and changes during the years ended December 31, 2009 and 2008, is presented as follows:

	Options	Weighted Average Grant-Date Fair Value
Outstanding as of December 31, 2007	389,504	$ 1,363,064
Granted	1,334,437	4,573,294
Vested	(996,556)	(3,568,335)
Forfeited or expired	(101,659)	(296,845)
Outstanding as of December 31, 2008	625,726	2,071,178
Granted	360,977	1,513,603
Vested	(598,500)	(2,252,177)
Forfeited or expired	(114,732)	(335,015)
Outstanding as of December 31, 2009	273,471	$ 997,589

(17) Stock-based compensation (continued)

A summary of the Company's restricted stock as of December 31, 2009 and 2008, and changes during the years ended December 31, 2009 and 2008, is presented as follows:

	Restricted Stock
Outstanding as of December 31, 2007	—
Granted	—
Vested	—
Outstanding as of December 31, 2008	—
Granted	403,030
Vested	—
Forfeited or expired	—
Outstanding as of December 31, 2009	403,030

(18) Segmented information

Subsequent to discontinuing the Ossatron® mobile service business and selling the veterinary business line (Note 3), the Company has only one line of business and substantially all assets are located in the United States.

(19) Quarterly results (unaudited)

Summary data relating to the results of operations for each quarter of the years ended December 31, 2009 and 2008, are as follows:

	Three months ended			
	March 31	June 30	September 30	December 31
Fiscal year 2009:				
Revenues	$ 262,082	$ 141,965	$ 134,771	$ 121,907
Gross profit	201,800	103,584	104,018	25,533
Loss from continuing operations, before income taxes	(2,145,951)	(1,678,090)	(2,696,755)	(2,665,961)
Income tax benefit — continuing operations	—	—	—	1,203,172
Loss from continuing operations, net of income taxes	(2,145,951)	(1,678,090)	(2,696,755)	(1,462,789)
Income (loss) from discontinued operations, before income taxes	322,485	2,751,094	(3,245)	(36,617)
Income tax expense — discontinued operations	—	—	—	(1,203,172)
Income (loss) from discontinued operations, after income taxes	322,485	2,751,094	(3,245)	(1,239,789)
Net income (loss)	(1,823,466)	1,073,004	(2,700,000)	(2,702,578)
Earnings (loss) per share				
Loss from continuing operations — basic	$ (0.20)	$ (0.15)	$ (0.24)	$ (0.12)
Loss from continuing operations — diluted	$ (0.20)	$ (0.15)	$ (0.24)	$ (0.12)
Income (loss) from discontinued operations — basic	$ 0.03	$ 0.25	$ —	$ (0.10)
Income (loss) from discontinued operations — diluted	$ 0.03	$ 0.25	$ —	$ (0.10)
Net income (loss) — basic	$ (0.17)	$ 0.10	$ (0.24)	$ (0.22)
Net income (loss) — diluted	$ (0.17)	$ 0.10	$ (0.24)	$ (0.22)
Weighted average shares outstanding — basic	11,009,657	11,009,657	11,092,990	12,509,657
Weighted average shares outstanding — diluted	11,009,657	11,009,657	11,092,990	12,509,657
Fiscal year 2008:				
Revenues	$ 331,280	$ 363,948	$ 167,423	$ 183,207
Gross profit	210,213	263,280	107,210	112,432
Loss from continuing operations, before income taxes	(2,837,992)	(2,752,966)	(2,917,459)	(3,218,346)
Income tax benefit — continuing operations	—	—	—	333,718
Loss from continuing operations, net of income taxes	(2,837,992)	(2,752,966)	(2,917,459)	(2,884,628)
Income (loss) from discontinued operations, before income taxes	(123,721)	242,850	565,534	1,633,182
Income tax expense — discontinued operations	—	—	—	(333,718)
Income (loss) from discontinued operations, after income taxes	(123,721)	242,850	565,534	1,299,464
Net loss	(2,961,713)	(2,510,116)	(2,351,925)	(1,585,164)
Earnings (loss) per share				
Loss from continuing operations — basic	$ (0.26)	$ (0.25)	$ (0.26)	$ (0.26)
Loss from continuing operations — diluted	$ (0.26)	$ (0.25)	$ (0.26)	$ (0.26)
Income (loss) from discontinued operations — basic	$ (0.01)	$ 0.02	$ 0.05	$ 0.12
Income (loss) from discontinued operations — diluted	$ (0.01)	$ 0.02	$ 0.05	$ 0.12
Net loss — basic	$ (0.27)	$ (0.23)	$ (0.21)	$ (0.14)
Net loss — diluted	$ (0.27)	$ (0.23)	$ (0.21)	$ (0.14)
Weighted average shares outstanding — basic	11,009,657	11,009,657	11,009,657	11,009,657
Weighted average shares outstanding — diluted	11,009,657	11,009,657	11,009,657	11,009,657

(20) Subsequent event

The Company has evaluated subsequent events through the date of issuance of the consolidated financial statements.

During March 2010, the Company issued two promissory notes totaling $400,000 to two stockholders. The notes bear interest at 5% per annum and are due in June, 2010.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SANUWAVE HEALTH, INC.

By: /s/ Christopher M. Cashman
Name: Christopher M. Cashman
Title: President and CEO

Dated: March 31, 2010

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

Signatures	Capacity	Date
By: /s/ Christopher M. Cashman Name: Christopher M. Cashman	Chief Executive Officer and President (Principal Executive Officer)	March 31, 2010
By: /s/ Barry J. Jenkins Name: Barry J. Jenkins	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2010
By: /s/ Kevin A. Richardson, II Name: Kevin A. Richardson, II	Director	March 31, 2010
By: /s/ John F. Nemelka Name: John F. Nemelka	Director	March 31, 2010
By: /s/ Thomas H. Robinson Name: Thomas H. Robinson	Director	March 31, 2010

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
4.1	Form of Class A Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.2	Form of Class B Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.3	Form of Amended and Restated Class C Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.4	Form of Amended Senior Note issued by SANUWAVE, Inc. to Prides Capital Fund I, L.P. and NightWatch Capital Partners II, L.P. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.5	Form of Promissory Note, dated August 1, 2005, issued by SANUWAVE, Inc. to HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.1	Form of Stock Repurchase Agreement, dated as of September 25, 2009, by and among Rub Music Enterprises, Inc. and certain stockholders of Rub Music Enterprises, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.2	Indemnification Agreement, dated September 25, 2009, by and among Rub Music Enterprises, Inc., SANUWAVE, Inc. and David N. Nemelka. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

Exhibit No.	Description
10.3	Form of Lock-Up Agreement, dated September 25, 2009, by and between certain stockholders of Rub Music Enterprises, Inc. and Rub Music Enterprises, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.4	Form of Lock-Up Agreement, dated September 2009, by and between certain shareholders of SANUWAVE, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.5	Form of Lock-Up Agreement, dated September 2009, by and between certain substantial shareholders of SANUWAVE, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.6	Employment Agreement, dated December 19, 2005, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.7	First Amendment to Employment Agreement, dated September 15, 2009, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.8	Amendment to Nonstatutory Stock Option Award and Nonstatutory Supplemental Agreements, dated September 15, 2009, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.9	Employment Agreement, dated April 10, 2006, by and between SANUWAVE, Inc. and Barry J. Jenkins. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.10	Amendment to Nonstatutory Stock Option Award and Nonstatutory Supplemental Agreements, dated September 15, 2009, by and between SANUWAVE, Inc. and Barry J. Jenkins. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.11	Management Stockholders Agreement, dated as of December 19, 2005, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.12	Amendment to Management Stockholders Agreement, dated as of October 24, 2006, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.13	Second Amendment to Management Stockholders Agreement, dated as of September 25, 2009, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

Exhibit No.	Description
21.1*	List of subsidiaries.
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Chief Executive Officer.
32.2*	Section 1350 Certification of the Chief Financial Officer.

* Filed herewith

Exhibit 21.1

List of Subsidiaries

Direct Subsidiary of SANUWAVE Health, Inc.

1. SANUWAVE, Inc., a Delaware corporation

Subsidiaries of SANUWAVE, Inc. — Indirect Subsidiaries of SANUWAVE Health, Inc.

2. Sanuwave Services, LLC, a Delaware limited liability company
3. HT Orthotripsy Management Company, LLC, a Delaware limited liability company
4. Sanuwave I, LLC, a Delaware limited liability company
5. Sanuwave Equipment, LLC, a Delaware limited liability company
6. Sanuwave AG, a company organized under the laws of Switzerland
7. Sanuwave Holding, AG, a company organized under the laws of Switzerland

EXHIBIT 31.1

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Christopher M. Cashman, certify that:

1. I have reviewed this annual report on Form 10-K of SANUWAVE Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2010

/s/ Christopher M. Cashman
Christopher M. Cashman
Chief Executive Officer and President

EXHIBIT 31.2

Certification of Chief Financial Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Barry J. Jenkins, certify that:

1. I have reviewed this annual report on Form 10-K of SANUWAVE Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2010

/s/ Barry J. Jenkins
Barry J. Jenkins
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION

In connection with the annual report of SANUWAVE Health, Inc. (the "Company") on Form 10-K for the year ended December 31, 2009 as filed with the Securities and Exchange Commission (the "Report"), I, Christopher M. Cashman, Chief Executive Officer and President of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 31, 2010

/s/ Christopher M. Cashman
Christopher M. Cashman
Chief Executive Officer and President

EXHIBIT 32.2

CERTIFICATION

In connection with the annual report of SANUWAVE Health, Inc. (the "Company") on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the "Report"), I, Barry J. Jenkins, Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

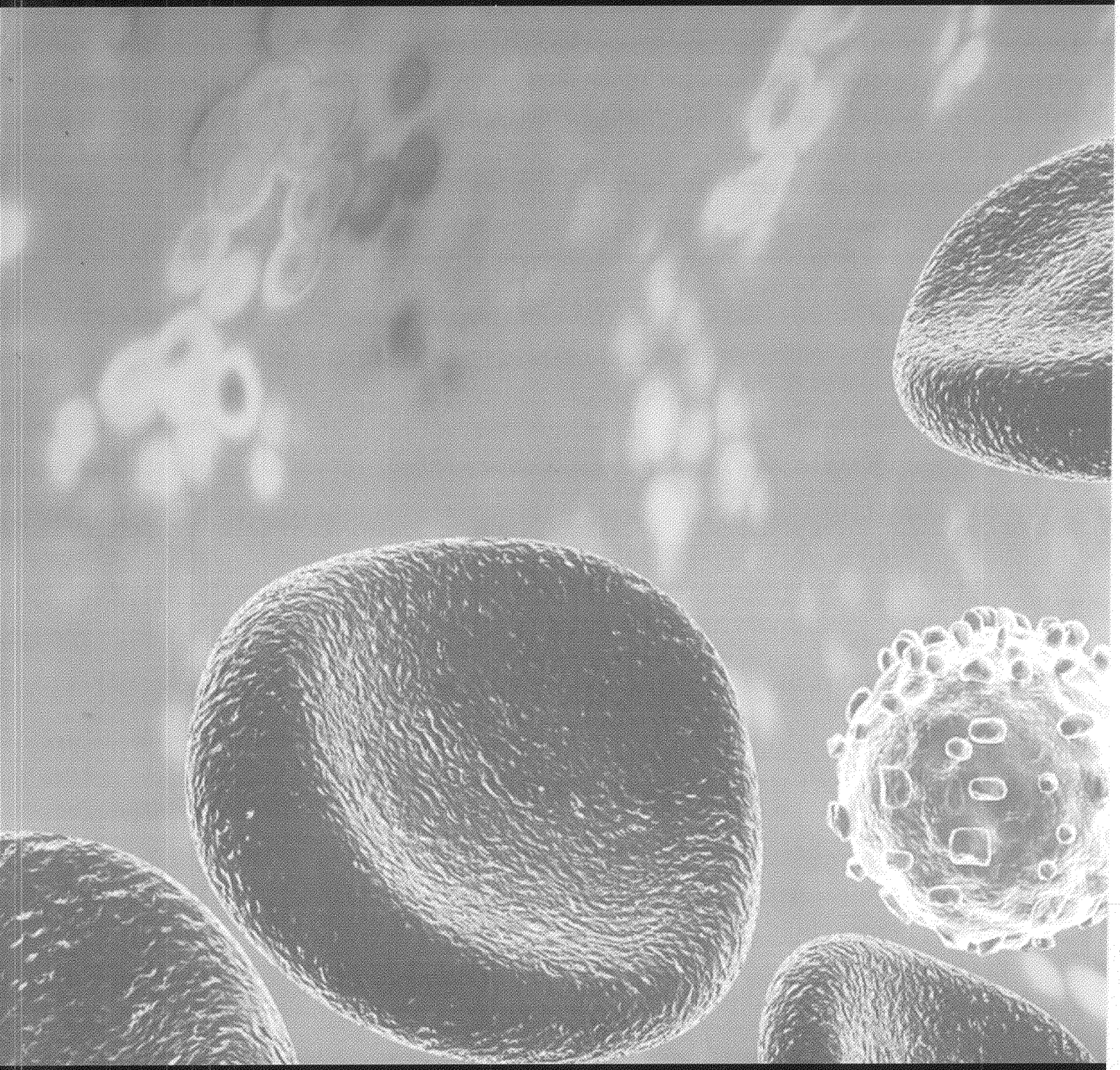
1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 31, 2010

/s/ Barry J. Jenkins

Barry J. Jenkins
Chief Financial Officer



11680 Great Oaks Way, Suite 350
Alpharetta, GA 30022
770.419.7525
email: investorrelations@sanuwave.com
www.sanuwave.com
SYM: SNWV