SANUWAVE Health, Inc.
Form 10-K
March 31, 2010

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission File Number 000-52985

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

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

(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. o Yes þ No

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

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

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ
		(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). o Yes þ 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.
Table of Contents

Table of Contents

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, believ 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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).

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

17

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 m