SANUWAVE Health, Inc.
Form S-1
May 10, 2011

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As filed with the Securities and Exchange Commission on May 10, 2011
Registration No. _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**3841**	**20-1176000**
(State or other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

11680 Great Oaks Way, Suite 350
Alpharetta, Georgia 30022
(770) 419-7525
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Christopher M. Cashman
President and Chief Executive Officer
SANUWAVE Health, Inc.
11680 Great Oaks Way, Suite 350
Alpharetta, Georgia 30022
(770) 419-7525
(Name, address, including zip code, and telephone number, including area code, of agent for service)
Copies of all communications, including communications sent to agent for service, should be sent to:

John C. Ethridge, Jr., Esq.
Smith, Gambrell & Russell, LLP
Promenade II, Suite 3100
1230 Peachtree Street, N.E.
Atlanta, Georgia 30309
(404) 815-3500

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: þ

If this Form is filed to registered additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement

for the same offering. o

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 definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per unit (2)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, $0.001 par value	2,804,593	$ 4.60	$ 12,901,128	$1,497.82
Common Stock, $0.001 par value (3)	2,897,673	$ 4.60	$ 13,329,296	$1,547.53
Total Registration Fee	5,702,266	$ 4.60	$ 26,230,424	$3,045.35

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares of common stock registered for resale by the selling stockholders also include such indeterminate number of shares of common stock as may be issued from time to time with respect to shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457 under the Securities Act of 1933, as amended, based on the per share average of the high and low reported prices for the common stock on the Over the Counter Bulletin Board as of May 5, 2011.

(3) Represents shares of common stock issuable upon the exercise of the warrants.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. Our selling stockholders may not sell these securities described herein until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell the securities and we are not soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Subject to Completion, Dated _____, 2011

5,702,266 Shares

Common Stock

This prospectus relates to the sale of up to 5,702,266 shares of our common stock. $0.001 par value (the Common Stock) by the selling stockholders listed in this prospectus. These shares consist of 2,804,593 outstanding shares of Common Stock and 2,897,673 shares of Common Stock issuable upon the exercise of warrants. The shares offered by this prospectus may be sold by the selling stockholders from time to time in the over-the-counter market or other national securities exchange or automated interdealer quotation system on which our Common Stock is then listed or quoted, through negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, or otherwise in compliance with the Plan of Distribution contained herein.

We are registering these shares following our April 2011 private placement. We will receive none of the proceeds from the sale of the shares by the selling stockholders. We may receive proceeds upon the exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol SNWV.OB. The high and low bid prices for shares of our Common Stock on May 5, 2011, were $4.60 and $4.60 per share, respectively, based upon bids that represent prices quoted by broker-dealers on the OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

An investment in these securities involves a high degree of risk.
Please carefully review the section titled Risk Factors beginning on page 5.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is _____, 2011

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PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary may not contain all of the information that you should consider before investing in our Common Stock. You should carefully read the entire prospectus, including Risk Factors and the consolidated financial statements, before making an investment decision.

Our Company

We are an emerging global regenerative medicine company focused on the development and commercialization of non-invasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. 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.

Product Overview

Our lead device product for the global wound care market, dermaPACE®, has recently completed its pivotal Phase III, Investigational Device Exemption (IDE) trial in the United States for the treatment of diabetic foot ulcers. We received permission by the United States Food and Drug Administration (the FDA) through the acceptance of our shell application in August 2010 to file the pre-market approval (PMA) for dermaPACE in a series of three sections or modules. The first module included preclinical data and results of prior clinical testing and was filed in December 2010. The second module, containing a quality manufacturing system review, was submitted in January 2011. We expect to file the third module containing data from the recently completed pivotal Phase III clinical trial of dermaPACE to treat diabetic foot ulcers, proposed product labeling and a summary of safety and effectiveness in the second quarter of 2011. The 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.

We research, design, manufacture, market and service our products worldwide and believe we have already 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, Evotron, and newly introduced orthoPACE devices in Europe.

We are focused on developing our PACE technology to activate healing in:

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

Market Trends

We are focused on the development of products that treat unmet medical needs in large market opportunities. Currently, there are limited biological or mechanical therapies to activate the healing and regeneration of tissue, bone and vascular structures. As baby boomers age, the incidence of their targeted diseases and musculoskeletal injuries and ailments will be far more prevalent. We believe that our 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. Diabetes is common, disabling and deadly. In the United States, diabetes has reached epidemic proportions. According to the American Diabetes Association, about 25.8 million people (8.3% of the total United States population) have diabetes, and nearly two million new cases are diagnosed in people aged 20 years or older each year. If current trends continue, 1 in 3 Americans will develop diabetes at some point in their lifetime, and those with diabetes will lose, on average, 10-15 years of life expectancy. Importantly, up to 25% of people with diabetes will develop a diabetic foot ulcer, resulting in 3 million diabetic foot ulcers annually in the United States alone. More than half of all foot ulcers will become infected, thus requiring hospitalization, and 1 in 5 will require an amputation that carries a high risk of mortality. Diabetes puts tremendous economic pressure on the United States healthcare system. In January 2011, the Centers for Disease Control and Prevention (the CDC) reported the total costs (direct and indirect) of diabetes in the United States is $174

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billion annually, and people with diagnosed diabetes have medical expenditures that are over two times higher than medical expenditures for people without diabetes. Hospitalization costs alone are $16,000 to $20,000 for a patient with a diabetic foot ulcer, and direct and indirect costs of an amputation range from $20,000 to $60,000 per patient. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need, yet in short supply, globally. According to the American Diabetes Association, by the year 2025 the prevalence of diabetes is expected to rise by 72% to 324 million people worldwide.

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

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.

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. 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.

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.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. We have a limited operating history and have incurred substantial losses since inception. We expect to continue to incur losses for the foreseeable future and are unable to predict the extent of future losses or when we will become profitable, if at all. All of our products are in various stages of development and clinical trials and have not yet received regulatory approval in the United States. Our ability to generate revenue in the future will depend heavily on the successful development and commercialization of our product candidates. Even if we succeed in developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and sustain profitability. We may be unable to maintain and protect our intellectual property, which could have a substantial impact on our ability to generate revenue. Our products are subject to regulation by governmental authorities in the United States and in other countries. Failure to comply with such regulations or to receive the necessary approvals or clearances for our product and product candidates may have a material adverse effect on our business.

Trading Market

Our common stock, $.001 par value (the Common Stock), is quoted on the Over-The-Counter Bulletin Board under the symbol SNWV.OB.

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Corporate Information

We were incorporated in the State of Nevada on May 6, 2004, under the name Rub Music Enterprises, Inc. (RME). SANUWAVE, Inc. was incorporated in the State of Delaware on July 21, 2005. In December 2006, Rub Music Enterprises, Inc. ceased operations and became a shell corporation.

On September 25, 2009, RME and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of RME (the Merger Sub) entered into a reverse 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) and a wholly-owned subsidiary of the Company.

In November 2009, we changed our name to SANUWAVE Health, Inc. Our principal executive offices are located at 11680 Great Oaks Way, Suite 350, Alpharetta, Georgia 30022, and our telephone number is (678) 581-6843. Our website address is *www.sanuwave.com*. The information on our website is not a part of this prospectus.

Unless the context requires otherwise, the words SANUWAVE, we, Company, us, and our in this prospec refer to SANUWAVE Health, Inc.

About this Offering

This prospectus relates to the public offering, which is not being underwritten, of up to 5,702,266 shares of our Common Stock by the selling stockholders listed in this prospectus. These shares consist of 2,804,593 outstanding shares of Common Stock and 2,897,673 shares of Common Stock issuable upon the exercise of warrants. The shares offered by this prospectus may be sold by the selling stockholders from time to time in the over-the-counter market or other national securities exchange or automated interdealer quotation system on which our Common Stock is then listed or quoted, through negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices. We will receive none of the proceeds from the sale of the shares by the selling stockholders. We may receive proceeds upon exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

The shares of Common Stock being offered by this prospectus relate to shares of Common Stock and warrants issued in our April 2011 private placement to 28 accredited investors of 2,804,593 shares of our Common Stock at a purchase price of $3.25 per share, for gross proceeds to the Company of $9,114,927. The net proceeds received by the Company were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of our Common Stock at an initial exercise price of $4.00 per share. Rodman & Renshaw, LLC, the placement agent for the private placement, was issued five-year warrants to purchase up to 93,080 shares of our Common Stock at an initial exercise price of $4.00 per share. For a more detailed discussion regarding the private placement, please see Selling Stockholders April 2011 Private Placement in this prospectus.

The number of shares being offered by this prospectus represents approximately 24.0% of our outstanding shares of Common Stock (assuming the exercise of the warrants included in the number of shares covered by this prospectus) as of May 5, 2011.

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THE OFFERING

Common Stock being offered by the selling stockholders:

Shares of Common Stock	2,804,593 shares
Shares of Common Stock that may be issued upon the exercise of warrants	2,897,673 shares
Total	5,702,266 shares
Common Stock outstanding	20,907,536 shares (1)
OTC Bulletin Board symbol	SNWV.OB
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares by the selling stockholders, except cash for the warrant exercise price upon exercise of the warrants, which would be used for working capital purposes.
Risk Factors	See Risk Factors beginning on page 5 and other information included in this prospectus for a discussion of factors you should consider before investing in shares of our Common Stock.

(1) The number of shares shown to be outstanding is based on the number of shares of our Common Stock outstanding as of May 5, 2011, and does not include shares reserved for issuance upon the exercise of warrants outstanding, or options granted or available under our equity compensation plans.

SUMMARY FINANCIAL INFORMATION

The summary financial information set forth below is derived from and should be read in conjunction with our consolidated financial statements, including the notes thereto, appearing at the end of this prospectus.

	Year Ended December 31, 2010	Year Ended December 31, 2009
Consolidated Statement of Operations Data		
Revenues	$ 728,446	$ 660,725
Net loss	$(14,922,441)	$ (6,153,040)
Weighted average shares outstanding	12,924,872	11,405,490
Net loss per share basic and diluted	$ (1.15)	$ (0.54)
Consolidated Balance Sheet Data (at end of period)		
Working capital (deficit)	$ (7,029,635)	$ (187,459)
Total assets	$ 3,029,299	$ 5,867,085
Total liabilities	$ 13,545,500	$11,751,399
Total stockholders equity (deficit)	$(10,516,201)	$ (5,884,314)

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RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus, including the consolidated financial statements and the related notes appearing at the end of this prospectus, before purchasing our Common Stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In any such event, the market price of our Common Stock could decline and you could lose all or part of your investment.

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 expenses for seeking FDA approval for our dermaPACE device and then commercialization in the United States after FDA approval. As of December 31, 2010, we had an accumulated deficit of $54.3 million. We continue to focus our expertise and future development efforts on the development of our PACE technology in wound care, orthopedic/spine, plastic/cosmetic and cardiac applications. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenues and we may never achieve or be able to maintain profitability.

Current economic conditions could adversely affect our operations.

According to the National Bureau of Economic Research, the United States economy was in a recession from December 2007 through June 2009. This economic downturn was the longest recession since World War II. The related instability of markets 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. In addition, any change in the economy as a result of this long recession may impact the demand for medical procedures that we are targeting with our product candidates, or may impact the pricing of our products. Since our anticipated United States product launch for our lead product device, dermaPACE, remains up to a year away, the impact of the recession on commercial markets for that product remains uncertain.

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.

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

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

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

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

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

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

We currently purchase most of our product component materials from single suppliers. If we are unable to obtain product component materials and other products from our suppliers that we depend on for our operations, our ability to deliver our products to market will likely be impeded.

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

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

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

As a small company with 29 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.

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

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

Regulatory Risks

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

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate will be safe and effective in advanced clinical trials involving larger numbers of patients, we will be unable to submit the necessary application to receive regulatory approval to commercialize the product candidate. We face risks that:

the product candidate may not prove to be safe or effective;

the product candidate s benefits may not outweigh its risks;

the results from 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.

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

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected. We cannot be sure that the FDA will not select a different center and/or different legal authority for our other product candidates, in which case the path to regulatory approval would be different and could be more lengthy and costly.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers, our contract manufacturers and our contract testing laboratories are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

warning letters;

fines and other monetary penalties;

unanticipated expenditures;

delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;

product recall or seizure;

interruption of manufacturing or clinical trials;

operating restrictions;

injunctions; and

criminal prosecutions.

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

testing;

manufacturing;

quality control;

labeling;

advertising;

promotion;

distribution;

export;

reporting to the FDA certain adverse experiences associated with the use of the products; and

obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

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

The FDA s requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers, contract manufacturers and contract laboratories. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in the United States Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

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

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

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

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

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

which those approvals are sought.

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

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

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

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

Patients may discontinue their participation in our clinical studies, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Clinical trials for our product candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged to be related to our product candidates under evaluation. If a large number of patients in any one of our studies discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of our product candidates.

In addition, the time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the following:

- the size of the patient population;
- the nature of the clinical protocol requirements;
- the availability of other treatments or marketed therapies (whether approved or experimental);
- our ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient eligibility criteria for the study.

Product quality or performance issues may be discovered through ongoing regulation by the FDA and by comparable international agencies, as well as through our internal standard quality process.

The medical device industry is subject to substantial regulation by the FDA and by comparable international agencies. In addition to requiring clearance or approval to market new or improved devices, we are subject to ongoing regulation as a device manufacturer. Governmental regulations cover many aspects of our operations, including quality systems, marketing and device reporting. As a result, we continually collect and analyze information about our

product quality and product performance through field observations, customer feedback and other quality metrics. If we fail to comply with applicable regulations or if post market safety issues arise, we could be subject to enforcement sanctions, our promotional practices may be restricted, and our marketed products could be subject to recall or otherwise impacted. Each of these potential actions could result in a material adverse effect on our operating results.

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

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

materials and specified waste products. The cost of compliance with these laws and regulations could be significant.

Risks Related to Intellectual Property

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

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

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

The degree of intellectual property protection for our technology is uncertain, and only limited intellectual property protection may be available for our product candidates, which may prevent us from gaining or keeping any competitive advantage against our competitors. Although we believe the patents that we own or license, and the patent applications that we own or license, generally provide us a competitive advantage, the patent positions of biotechnology, biopharmaceutical and medical device companies are generally highly uncertain, involve complex legal and factual questions and have been the subject of much litigation. Neither the United States Patent & Trademark Office nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Further, a court or other government agency could interpret our patents in a way such that the patents do not adequately cover our current or future product candidates. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

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

some of our academic institution licensees, evaluators, collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to protect our proprietary information or obtain patent protection in the future may be impaired, which could have a material adverse effect on our business.

In particular, we cannot assure you that:

- we or the owners or other inventors of the patents that we own or that have been licensed to us, or that may be issued or licensed to us in the future, were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our patent applications will result in issued patents;
- the patents and the patent applications that we own or that have been licensed to us, or that may be issued or licensed to us in the future, will provide a basis for commercially viable products or will provide us with any competitive advantages, or will not be challenged by third parties;

the patents and the patent applications that have been licensed to us are valid and enforceable;

we will develop additional proprietary technologies that are patentable;

we will be successful in enforcing the patents that we own or license and any patents that may be issued or licensed to us in the future against third parties;

the patents of third parties will not have an adverse effect on our ability to do business; or

our trade secrets and proprietary rights will remain confidential.

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

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

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

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

We cannot assure you that the patents that have been issued or licensed to us would be held valid by a court or administrative body or that we would be able to successfully enforce our patents against infringers, including our competitors. The issuance of a patent is not conclusive as to its validity or enforceability, and the validity and enforceability of a patent is susceptible to challenge on numerous legal grounds, including the possibility of

reexamination proceedings brought by third parties in the United States Patent & Trademark Office against issued patents and similar validity challenges under foreign patent laws. Challenges raised in patent infringement litigation brought by or against us may result in determinations that patents that have been issued or licensed to us or any patents that may be issued to us or our licensors in the future are invalid, unenforceable or otherwise subject to limitations. In the event of any such determinations, third parties may be able to use the discoveries or technologies claimed in these patents without paying licensing fees or royalties to us, which could significantly diminish the value of our intellectual property and our competitive advantage. Even if our patents are held to be enforceable, others may be able to design around our patents or develop products similar to our products that are not within the scope of any of our patents.

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

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

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

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

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

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

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

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

Litigation or any other proceeding relating to intellectual property rights, even if resolved in our favor, may cause us to incur significant expenses, divert the attention of our management and key personnel from other business concerns and, in certain cases, result in substantial additional expenses to license technologies from third parties. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An unfavorable outcome in any patent infringement suit or other adverse intellectual property proceeding could require us to pay substantial damages, including possible treble damages and attorneys fees, cease using our technology or developing or marketing our products, or require us to seek licenses, if available, of the disputed rights from other parties and potentially make significant payments to those parties. There is no guarantee that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms. Even if we are able to obtain rights to a third party s patented intellectual property, those rights may be nonexclusive and, therefore, our competitors may obtain access to the same

intellectual property. Ultimately, we may be unable to commercialize our product candidates or may have to cease some of our business operations as a result of patent infringement claims, which could materially harm our business. We cannot guarantee that our products or technologies will not conflict with the intellectual property rights of others.

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

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

Risks Related to Our Common Stock

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

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

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

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

- unforeseen developments during our pre-clinical activities and clinical trials;
- delays in timing of receipt of required regulatory approvals;
- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of any approved product;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using any of our approved products;
- inability to train a sufficient number of physicians to create a demand for any of our approved products;
- lack of financial resources to adequately support our operations;

difficulties in maintaining commercial scale manufacturing capacity and capability;

unforeseen problems with our third party manufacturers, service providers or specialty suppliers of certain raw materials;

unanticipated difficulties in operating in international markets;

unanticipated financial resources needed to respond to technological changes and increased competition;

unforeseen problems in attracting and retaining qualified personnel to market our approved products;

enactment of new legislation or administrative regulations;

the application to our business of new court decisions and regulatory interpretations;

claims that might be brought in excess of our insurance coverage;

the failure to comply with regulatory guidelines; and

the uncertainty in industry demand and patient wellness behavior as businesses and individuals suffer from the current economic downturn.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

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If adequate financing is not available, we may be required to delay, scale back or eliminate our operations. Consequently, our long-term viability would be threatened.

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

As of May 5, 2011, Prides Capital owned 47.1% of our outstanding Common Stock and NightWatch Capital owned 10.0% of our outstanding Common Stock on a beneficial ownership basis. In addition, Kevin A. Richardson, II, who is managing partner of Prides Capital, owns 12.9% of our outstanding Common Stock on a beneficial ownership basis. Mr. Richardson was appointed by Prides Capital and John F. Nemelka was appointed by NightWatch Capital to serve on our board of directors. For as long as Prides Capital and NightWatch Capital own a majority of our shares of Common Stock, they will be able to control the election of all of the members of our board of directors and control the vote of stockholders on other matters. For as long as they own a significant percentage of our outstanding stock, even if less than a majority, Prides Capital and NightWatch Capital will be able to control and exercise significant influence over our business affairs, including the general strategic direction of our business, the incurrence of indebtedness by us, the issuance of any additional equity securities, the repurchase of equity securities and the payment of dividends, and will have the power to determine or significantly influence the outcome of matters submitted to a vote of our stockholders, including mergers, consolidations, sales or dispositions of assets, reductions in share capital, other business combinations and amendments to our articles of incorporation. Prides Capital and NightWatch Capital may take actions with which you or we do not agree, including actions that delay, defer or prevent a change in control of our Company or that could adversely affect the market price of our Common Stock. In addition, they may take other action that might be favorable to them, but not favorable to us or our other stockholders. Also, if either Prides Capital or NightWatch Capital sells all or a portion of its interest in us, it may cause the value of your investment to decrease.

Our stock price is volatile.

The market price of our Common Stock is volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- changes in 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 can be limited under the SEC s penny stock regulations, which has an adverse effect on the liquidity of our Common Stock.

If trading price of our Common Stock is less than $5.00 per share, our Common Stock will be considered a penny stock, and trading in our Common Stock is subject to the requirements of Rule 15g-9 under the Securities Exchange Act of 1934, as amended (the Exchange Act). Under this rule, broker-dealers who recommend low-priced securities to persons other than established customers and accredited investors must satisfy special sales practice requirements. Generally, the broker-dealer must make an individualized written suitability determination for the purchaser and receive the purchaser s written consent prior to the transaction.

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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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933. Statements in this prospectus that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended (the Securities Act). Forward-looking statements convey our current expectations or forecasts of future events. All statements in this prospectus, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company s future financial results, operating results, business strategies, projected costs, products, competitive positions, management s plans and objectives for future operations, and industry trends. These forward-looking statements are based on management s estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, predict, potential negative of these terms, or other comparable terminology. These forward-looking statements include, among other things, statements about:

- market acceptance of and demand for dermaPACE and our product candidates;

regulatory actions that could adversely affect the price of or demand for our approved products;

our intellectual property portfolio;

timing of clinical studies and eventual FDA approval of our products;

our marketing and manufacturing capacity and strategy;

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estimates regarding our capital requirements, and anticipated timing of the need for additional funds;

product liability claims;

economic conditions that could adversely affect the level of demand for our products;

financial markets; and

the competitive environment.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in the section titled Risk Factors. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should read this prospectus and the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission (the SEC) to register the shares of our Common Stock being offered by this prospectus. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any reports, statements or other information that we file at the SEC s public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information regarding the public reference facilities. The SEC maintains a website, http://www.sec.gov that contains reports, proxy statements and information statements and other information regarding registrants that file electronically with the SEC, including us. Our SEC filings are also available to the public from commercial document retrieval services. Information contained on our website should not be considered part of this prospectus.

You may also request a copy of our filings at no cost by writing or telephoning us at:

SANUWAVE Health, Inc.
11680 Great Oaks Way, Suite 350
Alpharetta, Georgia 30022
Attention: Barry J. Jenkins, Chief Financial Officer
Telephone: (770) 419-7525

USE OF PROCEEDS

This prospectus relates to shares of our Common Stock that may be offered and sold from time to time by the selling stockholders who will receive all of the proceeds from the sale of the shares. We will not receive any proceeds from the sale of shares of Common Stock in this offering. We will bear all expenses of registration incurred in connection with this offering, but all commissions, selling and other expenses incurred by the selling stockholders to underwriters, agents, brokers and dealers will be borne by them. We estimate that our expenses in connection with the filing of the registration statement of which this prospectus is a part will be approximately $42,000.

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MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

Shares of our Common Stock are 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 closing 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:

	Price Range	
	High	**Low**
2011		
First Quarter	$5.50	$3.95

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

	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

See the cover page of this prospectus for a recent bid price of our Common Stock as reported by the OTC Bulletin Board.

Over-the-counter bid prices represent prices quoted by broker-dealers in the over-the-counter market. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

As of May 5, 2011, there were 20,907,536 shares of our Common Stock outstanding and approximately 86 holders of record of our Common Stock. However, we believe that there are more beneficial holders of our Common Stock as many beneficial holders hold their stock in street name.

This prospectus covers 5,702,266 shares of our Common Stock offered for sale by the selling stockholders, which consists of 2,804,593 outstanding shares of Common Stock and 2,897,673 shares of Common Stock issuable upon exercise of the warrants.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

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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 reflected in column (a)) (c)
Equity compensation plans approved by security holders			
Equity compensation plans not approved by security holders	2,992,796	$ 3.20	3,695,649
Total	2,992,796	$ 3.20	3,695,649

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Overview

We are an emerging global regenerative medicine company focused on the development and commercialization of non-invasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. 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, and newly introduced orthoPACE devices in Europe. Our lead product candidate for the global wound care market, dermaPACE, has received the European CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

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

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

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

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

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

Recent Developments

We have completed our multi-site, randomized, double-blind, sham controlled FDA investigational device exemption wound care clinical study focused on the healing of diabetic foot ulcers utilizing our lead product candidate, dermaPACE, and released top-line data. The primary study goal is to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham control, when both are combined with the current standard of care. The standard of care includes wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot. A total of 206 patients entered the dermaPACE study at 24 sites. The patients in the study were followed for a total of 24 weeks. The study s primary endpoint, wound closure, is defined as successful if the skin is 100% reepithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits. We have filed the first and second module of our PMA. We expect to file our final module with the FDA in the second quarter of 2011 and, pending a favorable response from the FDA, to launch dermaPACE in the United States in early 2012.

We launched in Europe the orthoPACE device intended for use in orthopedic, trauma and sports medicine indications following CE Mark approval in June 2010. The device features a new, unique applicator that is less painful for some indications and may reduce or completely eliminate anesthesia for some patients. In the orthopedic setting, the orthoPACE will initially be used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs.

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.

We believe that these 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

Our independent registered public accounting firm has issued a going concern statement in its report on our consolidated financial statements for the year ended December 31, 2010, stating that we had a net loss and negative cash flows from operations in fiscal 2010, and that we have an accumulated deficit. Accordingly, those conditions raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from this going-concern uncertainty.

On April 8, 2011, we completed a private placement to 28 institutional and individual accredited investors of 2,804,593 shares of our Common Stock at a purchase price of $3.25 per share, for gross proceeds of $9,114,927. The net proceeds received by the Company were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of our Common Stock at an initial exercise price of $4.00 per warrant. The net proceeds from the private placement, following the payment of offering-related expenses, are being used by us for working capital and other general corporate purposes.

On April 4, 2011, the note holders of our amended senior notes (the Notes) exchanged the unpaid principal and interest balance of the Notes which totaled $4,413,908 in consideration for the issuance of 1,358,126 shares of our Common Stock. In addition, in connection with this transaction, we issued to the note holders an aggregate total of 679,064 warrants to purchase shares of Common Stock at an exercise price of $4.00 per warrant. Each warrant

represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after five years.

In January 2011, we raised $3,900,334 from a group of accredited investors through the exercise of options they received in 2010 as part of a purchase of a unit which consisted of: (i) one share of Common Stock; (ii) a two-year Common Stock purchase warrant (the Class D Warrant) to purchase one share of Common Stock, at an exercise price of $2.00; and (iii) an option (the Option), which, as amended expired

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on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit.

Since our inception in 2005, we have funded our operations from the sale of capital stock, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009, and product sales. At December 31, 2010, the balance of cash and cash equivalents totaled $417,457.

We continue to incur research and development expenses for clinical trials and the development of products for additional indications. We expect to continue to incur significant research and development expenses as a result of new and ongoing clinical and pre-clinical studies in the United States and in Europe, as well as expenses associated with regulatory filings. 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. We will require additional capital to continue to implement our business strategies. There can be no assurance that we will be successful in raising such capital. See Liquidity and Capital Resources.

Since our inception, we have incurred losses from operations each year. As of December 31, 2010, we had an accumulated deficit of $54.3 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, clinical trials and the FDA approval process and as we prepare for a future sales network to represent our products. We incurred a net loss of $14.9 million and $6.2 million during the years ended December 31, 2010 and 2009, respectively. We had a working capital deficiency of $7,029,635 and $187,459 at December 31, 2010 and 2009, respectively. These operating losses and working capital deficiency create an uncertainty about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, promissory notes or other potential financing will provide the necessary funding for us to continue as a going concern.

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

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of successful marketing, sales and distribution;
- the cost and timing associated with establishing reimbursement for our products;
- the timing and results of our pre-clinical research programs;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior as businesses and individuals suffer from the current economic recession.

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth under the section entitled Risk Factors Risks Related to Our Business.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to 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 future period.

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While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements accompanying this prospectus, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

Research and Development Costs

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

Inventory Valuation

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

Inventory is carried at the lower of cost or market, which is valued using first in, first out (FIFO), and consists primarily of devices and the component material 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 which was assumed by the Company following the Merger. On November 1, 2010, the board of directors of the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the Amended Plan). The Amended Plan provides that stock options, and other equity interests or equity-based incentives, may be granted to key personnel and directors at the fair value exercise price at the time the option is granted which is approved by the Company s board of directors. The maximum term of any option granted pursuant to the Amended Plan is ten years from the date of grant.

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

Income Taxes

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

realize the net deferred tax asset in future years.

We have adopted a provision of ASC 740, *Income Taxes* (formerly FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48)). ASC 740 specifies the way public companies are to account for uncertainties in income tax reporting, and prescribes a methodology for recognizing, reversing, and measuring the tax benefits of a tax position taken, or expected to be taken, in a tax return. ASC 740 requires the evaluation of tax positions taken or expected to be taken in the course of preparing the Company s tax returns to determine

whether the tax positions would more-likely-than-not be sustained if challenged by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax benefit or expense in the current year.

Results of Operations for the Years ended December 31, 2010 and 2009

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2010 were $728,446, compared to $660,725 for the same period in 2009, an increase of $67,721, or 10%. Revenues resulted primarily from sales in Europe of our new product orthoPACE for orthopedic, trauma and sports medicine indications and from sales in Europe of our legacy Evotron device and the related applicators for these devices.

Cost of revenues for the year ended December 31, 2010 was $250,326, compared to $225,790 for the same period in 2009. Gross profit as a percentage of revenues was 66% in 2010 and 2009. The gross profit in 2010 remained consistent with 2009 due to a similar mix of devices and applicators sold in each year.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2010 were $3,879,146, compared to $3,387,204 for the same period in 2009, an increase of $491,942, or 15%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical related consultants, contract manufacturer development costs and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs. Research and development costs increased in 2010 as compared to the same period in 2009 due to higher costs of the clinical trial of dermaPACE for diabetic foot ulcers in the United States as enrollment ended during the first quarter of 2010 and statisticians and consultants were engaged to assist in the patient follow-up and data compiling phases of the clinical trial.

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

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2010 were $7,100,621, compared to $5,026,425 for the same period in 2009, an increase of $2,074,196, or 41%. General and administrative expenses include the non-cash compensation costs for stock compensation of $3,037,634 and $1,078,128 for the years ended December 31, 2010 and 2009, respectively. The increase in non-cash compensation costs for stock compensation of $1,959,506 for the year ended December 31, 2010, as compared to the same period in 2009, was primarily due to a shorter requisite period on new grants of options to employees and directors of the Company in 2010 as compared to 2009.

Excluding the non-cash compensation costs for stock compensation, general and administrative expenses were $4,062,987 for the year ended December 31, 2010, as compared to $3,948,297 for the same period in 2009, an increase of $114,690, or 3%.

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

Depreciation, Amortization and Write Down of Assets Held for Sale

Depreciation for the year ended December 31, 2010 was $829,576, compared to $365,108 for the same period in 2009, an increase of $464,468, or 127%. On October 31, 2008, the Company discontinued its Ossatron mobile service business and accordingly displayed the related assets of this business as discontinued operations. As of October 1, 2009, management determined that the used Ossatron device fixed assets and related parts inventory should be reclassified to continuing operations as it was not likely the used devices would be sold within the next twelve months. Therefore, depreciation expense on the used Ossatron device fixed assets was restarted at October 1, 2009. As of December 31, 2010, we recorded additional depreciation expense of $201,153 to fully depreciate the used Ossatron devices and recorded a write down of assets held for sale of $169,581 to fully reserve for the related parts

inventory for these devices. As of December 31, 2010, management determined that the market for selling the used Ossatron mobile service devices was not probable due to the age of the devices and changes in international electrical standards for which the devices are no longer compliant. Management currently has no plans to utilize these devices in the United States. The combination of these factors contributed to management s decision to write down these assets.

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Amortization for the year ended December 31, 2010 was $306,757, compared to $306,756 for the same period in 2009.

Other Income (Expense)

On June 3, 2009, we sold our veterinary division to Pulse Veterinary Technologies, LLC (Pulse Vet). Under terms of the asset purchase agreement, we will continue to provide production services at the direction of Pulse Vet for a fee until April 30, 2012, unless Pulse Vet elects to terminate the agreement at an earlier date. The income for these transitional services was $360,125 and $230,625 for the years ended December 31, 2010 and 2009, respectively, an increase of $129,500 or 56%. The increase was due to a full year of providing operational services in 2010, partially offset by accounting and IT support services that Pulse Vet discontinued in 2009.

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

Interest expense for the year ended December 31, 2010 was $961,585, compared to $739,847 for the same period in 2009, an increase of $221,738, or 30%. The increase was primarily due to interest accruing at 15% per annum on notes payable, related parties, totaling $2,125,000 issued during the year ended December 31, 2009, which were outstanding throughout 2010.

Provision for Income Taxes

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

At December 31, 2010, we had federal net operating loss carryforwards of approximately $40.9 million that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Income from Discontinued Operations

On June 3, 2009, we sold our veterinary division for $3,500,000 in cash to Pulse Vet and recognized a gain, net of taxes, of $1,486,345. The income from discontinued operations, net of taxes, was $344,200 for the year ended December 31, 2009.

Net Loss

Net loss for the year ended December 31, 2010 was $14,922,441, or ($1.15) per basic and diluted share, compared to a net loss of $6,153,040, or ($0.54) per basic and diluted share, for the year ended December 31, 2009. The loss from continuing operations was $14,922,441, or ($1.15) per basic and diluted share, for the year ended December 31, 2010, compared to a loss from continuing operations of $7,983,585, or ($0.70) per basic and diluted share, for the year ended December 31, 2009. We anticipate that our operating losses will continue over the next several years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products.

Liquidity and Capital Resources

We incurred a net loss of $14,922,441 and $6,153,040 for the years ended December 31, 2010 and 2009, respectively. These operating losses create uncertainty about our ability to continue as a going concern. Although no assurances can be given, management of the Company believes that potential additional issuances of equity,

promissory notes, or other potential financing will provide the necessary funding for the Company to continue as a going concern. Our condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. We are dependent upon future capital contributions or financing to fund ongoing operations. At December 31, 2010, we had $417,457 in cash and cash equivalents held in three financial institutions.

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We expect to devote substantial resources to continue our research and development efforts, including clinical trials. Because of the significant time it will take for our products to complete the clinical trial process, and for us to obtain approval from regulatory authorities and successfully commercialize our products, we will require substantial additional capital resources. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control.

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

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

Between September 30, 2010, and December 7, 2010, we issued 925,000 units to certain accredited investors for an aggregate total purchase price of $1,850,000. Each unit was sold to the new investors at a purchase price of $2.00 per unit. As a result of the offerings, we sold 925,000 units which consisted of 925,000 shares of Common Stock, 925,000 Class D warrants and 925,000 options, which, as amended, expired on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit.

As of December 31, 2010, the option holders exercised 101,163 options for total gross proceeds of $202,326 to us. In connection with the exercise of the options, we issued 101,163 shares of Common Stock and 101,163 Class D warrants.

Subsequent to year end December 31, 2010, between January 1 and January 31, 2011, the option holders exercised 1,950,167 options for total gross proceeds of $3,900,334 to us. In connection with the exercise of options, we issued 1,950,167 shares of Common Stock and 1,950,167 Class D warrants. The 132,500 options that remained unexercised at January 31, 2011 expired by their terms.

On April 8, 2011, we completed a private placement to 28 institutional and individual accredited investors of 2,804,593 shares of our Common Stock at a purchase price of $3.25 per share, for gross proceeds of $9,114,927. The net proceeds received by the Company were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of our Common Stock at an initial exercise price of $4.00 per warrant. The net proceeds from the private placement, following the payment of offering-related expenses, are being used by us for working capital and other general corporate purposes.

On April 4, 2011, the note holders of our amended senior notes (the Notes) cancelled the unpaid principal and interest balance of the Notes which totaled $4,413,908 in consideration for the issuance of 1,358,126 shares of our Common Stock. In addition, in connection with this transaction, we issued to the note holders an aggregate total of 679,064 warrants to purchase shares of Common Stock at an exercise price of $4.00 per warrant. Each warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after five years.

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

For the year ended December 31, 2009, net cash used by continuing operations for operating activities was $5,513,688, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by continuing operations for financing activities for the year ended December 31, 2009 was $3,694,929, which consisted of the proceeds from the issuance of notes payable to related parties of $2,125,000 and the sale of Common Stock to certain accredited investors of $1,819,844 offset by the repurchase of Common Stock of $180,000 and payment of development period liabilities of $69,915 prior to the Merger. Net cash used by discontinued operations for operating activities was $758,244 for the year ended December 31, 2009. Net cash provided by discontinued operations for investing activities was $3,601,772 for the year ended December 31, 2009 from the sale of the veterinarian division. Cash and cash equivalents increased by $1,242,743 for the year ended December 31, 2009.

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Segment Information

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

Other Comprehensive Income (Loss)

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

Contractual Obligations

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

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

In April 2007, we entered into a lease agreement for the production and research and development office for 5,168 square feet of space. Under the terms of the lease, we pay monthly rent of $8,075, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the lease expired on July 31, 2010, and we have extended the lease until October 31, 2012.

We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantities of product component materials for our products through the development, clinical testing and commercialization phases. We have contractual obligations under a supply agreement with Swisstronics Contract Manufacturing AG for the manufacture of our devices.

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, we entered into two notes with HealthTronics for $2,000,000 each. The notes bear interest at 6% annually. Quarterly interest through June 30, 2010 was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal is due August 1, 2015. Accrued interest on the notes not payable until August 2015 totaled $1,372,743 and $1,215,253 at December 31, 2010 and 2009, respectively.

During the period October 2008 through May, 2009 we issued notes payable to Prides Capital Fund I, L.P. for $3,125,000 in total and one note payable to NightWatch Capital Partners II, L.P. for $75,000. The notes payable bear interest at 15% annually. Quarterly interest through December 31, 2010, was accrued and added to the principal balance. Unpaid accrued interest and principal is due September 30, 2011. All or any portion of the unpaid principal can be converted into Common Stock with a conversion price of $2.92 per share. Accrued interest on the notes payable totaled $1,047,290 and $472,728 at December 31, 2010 and 2009, respectively. Subsequent to the fiscal year ended December 31, 2010, on April 4, 2011, the note holders exchanged the unpaid principal and interest balance of the notes payable which totaled $4,413,908 in consideration for the issuance of 1,358,126 shares of our Common Stock. In addition, in connection with this transaction, we issued to the note holders an aggregate total of 679,064 warrants to purchase shares of Common Stock at an exercise price of $4.00 per warrant. Each warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after five years.

Recently Issued Accounting Standards

Fair Value Measurements and Disclosures

In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-06, *Fair Value Measurements and Disclosures Topic 855* (ASU 2010-06). ASU 2010-06 provides amendments to ASC 820-10, *Fair Value Measurements* (ASC 820-10). ASC 820-10 defines fair value, establishes a framework for measuring fair value hierarchy for assets and liabilities measured at fair value, and requires expanded

disclosures about fair value measurements. The ASC 820-10 hierarchy ranks the

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quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the three categories (level 1, level 2 or level 3). ASU 2010-06 provides amendments to ASC 820-10 to require new disclosures for transfers in and out of levels 1 and 2, as well as a reconciliation of activity within level 3. Furthermore, ASU 2010-06 provides amendments that clarify existing disclosures regarding levels of disaggregation and inputs and valuation techniques. The new disclosures and clarifications of existing disclosures required by ASU 2010-06 are effective for interim and annual reporting periods beginning after December 15, 2009 (except for disclosures in the reconciliation of activity within level 3, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years). We adopted ASU 2010-06 as of January 1, 2010, and the adoption did not have a material impact on our consolidated financial statements.

Subsequent Events

In February 2010, the FASB issued ASU 2010-09, *Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements* (ASU 2010-09), to amend ASC 855, *Subsequent Events* (ASC 855). ASC 855, which was originally issued by the FASB in May 2009 (as SFAS No. 165, Subsequent Events), provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. ASC 855 distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. As a result of ASU 2010-09, companies are not required to disclose the date through which management evaluated subsequent events in the financial statements, either in originally issued financial statements or reissued financial statements. ASC 855 was effective for interim and annual periods ending after September 15, 2009, and ASU 2010-09 was effective immediately. We have evaluated subsequent events in accordance with ASU 2010-09, and the evaluation did not have a material impact on our consolidated financial statements.

Off-Balance Sheet Arrangements

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

Effects of Inflation

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

BUSINESS

Overview

We are an emerging global regenerative medicine company focused on the development and commercialization of non-invasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. 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.

Our lead device product for the global wound care market, dermaPACE, has recently completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers. We received permission by the FDA through the acceptance of our shell application in August 2010 to file the PMA for dermaPACE in a series of three sections or modules. This first module included preclinical data and results of prior clinical testing and was filed in December 2010. The second module containing a quality manufacturing system review was submitted in January 2011. We expect to file the third module containing data from the recently completed pivotal Phase III clinical trial of dermaPACE to treat diabetic foot ulcers, proposed product labeling and a summary of safety and effectiveness in the second quarter of 2011. The dermaPACE has received the European CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

We research, design, manufacture, market and service our products worldwide and believe we have already 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, Evotron, and newly introduced orthoPACE devices in Europe.

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We are focused on developing our PACE technology to activate healing in:

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

We believe our experience from our preclinical research and the clinical use of our predecessor legacy devices in Europe and Asia, as well as our Ossatron device in the United States, demonstrates the safety, clinical utility and efficacy of 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.

Organization; Reverse Merger Transaction

The Company is a corporation organized and existing under the laws of the State of Nevada. The Company was incorporated on May 6, 2004. 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., a Delaware corporation. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, Inc., with SANUWAVE, Inc. as the surviving entity (the Merger) and a wholly- owned subsidiary of the Company. 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, Class A warrants to purchase 1,106,627 shares of the Company s Common Stock at $4.00 per share, and Class B 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 Class C warrants outstanding to purchase the Company s Common Stock at $4.00 per share.

As a result of the Merger and the 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 this Merger. The Company was a shell company as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act) immediately prior to the Merger. 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.

Pulsed Acoustic Cellular Expression (PACE) Technology

Our PACE product candidates, including our lead product candidate, dermaPACE, utilize high energy, acoustic pressure waves in the shockwave 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 activation of a broad spectrum of cellular events critical for the initiation and progression of healing.

High energy, acoustic pressure waves in the shockwave spectrum are the primary component of our previously developed product, Ossatron, which was approved 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.

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dermaPACE Our lead product candidate

We have completed our multi-site, randomized, double-blind, sham controlled FDA IDE wound care clinical study focused on the healing of diabetic foot ulcers utilizing our lead product candidate, dermaPACE, and released top-line data. The primary study goal is to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham control, when both are combined with the current standard of care. The standard of care includes wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot. A total of 206 patients were enrolled and randomized in the dermaPACE study at 24 sites. The patients in the study were followed for a total of 24 weeks. The study s primary endpoint of wound closure was defined as 100% skin re-epithelialization without drainage or dressing requirements confirmed at two consecutive visits, 2-4 weeks apart. Secondary clinical trial endpoints included time to closure, reduction in total wound surface area and volume, rate of improvement, long-term safety, and skin appearance and pain assessments.

Unlike many other chronic wound trials conducted in the diabetic patient population, there were two important, rigorous elements incorporated in the dermaPACE study design: double-blind (patient and principal investigator) randomization, and elimination of the option to close the target ulcer surgically or by other primary means. Maintaining the double-blind in this device trial restricted the knowledge of the treatment assignment so not to influence how a patient was treated or maintained on study and evaluated. This eliminated unintended human bias and qualifies this research as level 1 evidence, allowing the results to be accepted at face value. By not allowing the clinical investigators to surgically close the target ulcer in this clinical trial, the results provide a clear and unbiased view of the granulation and epithelialization process attributable to dermaPACE alone.

Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although this result was not statistically significant. Based on the pure, controlled design of the study, which blinded both investigators and patients and restricted investigators from closing wounds surgically, we analyzed a clinically relevant = 90% wound closure endpoint that demonstrated statistical significance (p=0.0161) in favor of dermaPACE (51/107, 48%) compared to patients randomized to receive Sham control (31/99, 31%). The median wound closure exceeded 99% for the dermaPACE treated patients who achieved at least 90% wound closure, and these patients had only a 4.5% recurrence rate at 24 weeks.

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

Based on the results of the clinical trial, the dermaPACE was shown to:

- significantly accelerate the rate of diabetic foot ulcer closure;
- cause highly significant reductions in ulcer size;
- have an extremely low rate of ulcer recurrence; and
- not be associated with any device-related adverse events.

We have filed the first two modules of our PMA. We expect to file our final module with the FDA in the second quarter of 2011 and, pending a favorable response from the FDA, to launch dermaPACE in the United States in early 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. These discussions will focus on building knowledge of dermaPACE and educating to the positive value proposition compared to existing alternatives. 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 and less burdensome required procedures.

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

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Currently, there are limited biological or mechanical therapies to activate the healing and regeneration of tissue, bone and vascular structures. As baby boomers age, the incidence of their targeted diseases and musculoskeletal injuries and ailments will be far more prevalent. We believe that our 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. Diabetes is common, disabling and deadly. In the United States, diabetes has reached epidemic proportions. According to the American Diabetes Association, about 25.8 million people (8.3% of the total United States population) have diabetes, and nearly two million new cases are diagnosed in people aged 20 years or older each year. If current trends continue, 1 in 3 Americans will develop diabetes at some point in their lifetime, and those with diabetes will lose, on average, 10-15 years of life expectancy. Importantly, up to 25% of people with diabetes will develop a diabetic foot ulcer, resulting in 3 million diabetic foot ulcers annually in the United States alone. More than half of all foot ulcers will become infected, thus requiring hospitalization, and 1 in 5 will require an amputation that carries a high risk of mortality. Diabetes puts tremendous economic pressure on the United States healthcare system. In January 2011, the Centers for Disease Control and Prevention (the CDC) reported the total costs (direct and indirect) of diabetes in the United States is $174 billion annually, and people with diagnosed diabetes have medical expenditures that are over two times higher than medical expenditures for people without diabetes. Hospitalization costs alone are $16,000 to $20,000 for a patient with a diabetic foot ulcer, and direct and indirect costs of an amputation range from $20,000 to $60,000 per patient. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need, yet in short supply, globally. According to the American Diabetes Association, by the year 2025 the prevalence of diabetes is expected to rise by 72% to 324 million people worldwide.

A majority of challenging wounds are non-healing chronic wounds. These wounds often involve physiologic, complex and multiple complications such as reduced blood supply, compromised lymphatic systems or immune deficiencies that interfere with the body s normal wound healing processes. In addition, diabetic ulcers and pressure ulcers are often slow-to-heal wounds. These wounds often develop due to a patient s impaired vascular and tissue repair capabilities. These conditions can also inhibit a patient s healing process, and often fail to heal for many months, and sometimes, for several years. Wounds that are difficult to treat do not always respond to traditional therapies, which include hydrocolloids, hydrogels and alginates. 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 non-invasive treatment is designed to elicit the body s own healing response. 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.

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 device has been used safely in Europe and Asia for various types of acute and chronic wounds.

Developing Product Opportunities Orthopedic and Spine

We launched the orthoPACE device in Europe which is intended for use in orthopedic, trauma and sports medicine indications following CE Mark approval in June 2010. The device features a new, unique applicator that is less painful for some indications and may reduce or completely eliminate anesthesia for some patients. In the orthopedic setting, the orthoPACE will initially be used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs.

We 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.

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.

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Trauma injuries are acute and result from any physical damage to the body caused by violence or accident or fracture. Surgical treatment of traumatic fractures often involves fixation with metallic plates, screws and rods (internal fixation) and include off-loading to prevent motion, permitting the body to initiate a healing response. In the United States, six million traumatic fractures are treated each year, and over one million internal fixation procedures are performed annually. The prevalence of non-union among these fractures is between 2.5% and 10.0% depending on the fracture type and risk factors such as diabetes and smoking history or other systemic diseases. At the time of surgery, adjunctive agents (such as autograft, cadaver bone and synthetic filling materials) are often implanted along with internal fixation to fill bony gaps or facilitate the healing process to avoid delayed union or non-union (incomplete fracture healing) results. Both pre-clinical and clinical investigations have shown positive results, suggesting our technology could potentially be developed as an adjunct to these surgeries or primary treatment protocol for delayed or non-union events.

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

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. PACE has been shown to be safe and effective in a pilot, rabbit model.

Market Trends

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

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

With the success of negative pressure wound therapy devices in the wound care market over the last 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 biological response activating devices that are applied non-invasively and seek to activate the body s own capabilities for regeneration of tissue at injury sites in a

cost-effective manner.

Strategy

Our objective is to be a leader in the development and commercialization of novel, biological response activating devices to treat tissue, musculoskeletal and vascular structure conditions. Our main vehicle for growth is the development and commercialization of our PACE technology. Our immediate goal involves leveraging the knowledge we gained from our existing human heel and elbow indications to enter the advanced wound care market with innovative treatments.

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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, orthopedic/spine, plastic/cosmetic and cardiac indications.

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

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

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

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

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

In the United States, we plan to build a 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 physician relationships. Outside the United States, we intend to utilize our distributor relationships for product introduction and adoption in local markets.

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

The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in many countries, we may be required to produce clinical data, which may involve more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies.

Scientific Advisors

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

We pay consulting fees to members of our scientific advisory board for the services they provide to us, in addition to reimbursing them for incurred expenses. The amounts vary depending on the nature of the services. We paid our advisors aggregate consulting fees and reimbursements of $90,126 and $74,100 for the years ended December 31, 2010 and 2009, respectively.

Sales, Marketing and Distribution

We intend to establish a direct sales force in the wound care market that will market our products in the United States. The direct sales 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 physician and care giver customers. We expect to have a 50-person sales force in the United States

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by the end of 2013 that will represent our initial dermaPACE commercial efforts after receiving FDA approval to market the device in the United States.

Outside the United States, we intend to employ distributors to represent our products in our respective international markets. These distributors will be selected based on their existing business relationships and the ability of their sales force and distribution capabilities to effectively penetrate the market with our PACE product line. In addition, we will rely on these distributors to manage physical distribution, customer service and billing services for our international customers.

Manufacturing

We have developed a network of suppliers, manufacturers and contract service providers to provide sufficient quantities of our products and product candidates through the development and clinical testing phases.

We have a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our products and product candidates. Our generator boxes are manufactured in accordance with applicable quality standards (EN ISO 13485) and applicable industry and regulatory standards. We produce the applicators and applicator kits for our products. In addition, we program and load software and perform the final product testing and certifications internally for all of our devices.

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

Intellectual Property

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

Patents

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

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

We are the assignee of fourteen issued United States patents and ten issued foreign patents. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations, piezoelectric fiber shockwave devices, chemical components for shockwave generation and detachable therapy heads with data

storage. Our United States patents also include patent claims directed to methods of using acoustic shockwaves, including shockwave devices such as our products, to treat ischemic conditions, spinal cord scar tissue and spinal injuries, body tissues under positive pressure, bone surface gaps, and, within particular treatment parameters, diabetic foot ulcers and pressure sores. While such patented method claims may provide patent protection against certain indirect infringing promotion and sales activities of competing manufacturers and distributors, certain medical methods performed by medical practitioners or related health care entities may be subject to exemption from potential infringement claims under 35 U.S.C. § 287(c) and, therefore, may limit enforcement of

claims of our method patents as compared to device and non-medical method patents.

We also currently maintain twelve United States non-provisional applications and twelve 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 in June 2009, we have also granted certain exclusive and non-exclusive patent license rights to Pulse Veterinary Technologies, LLC under most of our patent portfolio to utilize shockwave technologies in the field of non-human mammals.

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

If we become involved in future litigation or any other adverse intellectual property proceeding, for example, as a result of an alleged infringement, or a third party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, including treble damages, invalidation of our intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business, financial condition and results of operation. In addition, any claims relating to the infringement of third party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation, 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 and dermaPACE® in the United States. We have filed pending trademark applications for dermaPACE® in Canada and received registrations in the European Community, Japan, South Korea, Switzerland, Taiwan and under the Madrid Protocol (including the United States). We have filed pending trademark applications for angioPACE in the United States and received registrations in Australia, Canada, the European Community and Switzerland. We have received

trademark registrations for PACE and Pulsed Acoustic Cellular Expression in the European Community, China, Hong Kong, Singapore, Switzerland, Taiwan and have pending applications in Canada and the United States. We have filed pending applications for orthoPACE, DAP Diffused Acoustic Pressure, and Profile in the United States. We also maintain trademark registrations for the marks Ossatron® (United States and Germany), evoPACE® (Australia, the European Community and Switzerland), Evotron® (United States, Germany and Switzerland), Evotrode® (Germany and Switzerland), Healing Today. Curing Tomorrow. ® (United States), HMT® (Switzerland), orthoPACE® (the European Community), Orthotripsy® (United States), Reflectron® (Germany and Switzerland), Reflectrode® (Germany and Switzerland), CSWT® (Switzerland), OSWT® (Switzerland) and TSWT® (Switzerland).

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Potential Intellectual Property Issues

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

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

Third parties that license our proprietary rights, such as trademarks, patented technology or copyrighted material, may also take actions that diminish the value of our proprietary rights or reputation. In addition, the steps we take to protect our proprietary rights may not be adequate and third parties may infringe or misappropriate our copyrights, trademarks, trade dress, patents and similar proprietary rights.

We collaborate with other persons and entities on research, development and commercialization activities and expect to do so in the future. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, researchers, licensors, licensees and consultants. In addition, other parties may circumvent any proprietary protection that we do have. As a result, we may not be able to maintain our proprietary position.

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

Competition

We believe the advanced wound care market is dramatically underserved. Current technologies developed by Kinetic Concepts, Inc. (KCI), Advanced BioHealing, Inc., Organogenesis, Inc., Smith & Nephew plc, Integra LifeSciences Holdings Corporation and Systagenix Wound Management (US), Inc. 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 therapy (NPWT) device that applies suction to debride and better manage wounds. KCI successfully launched the V.A.C. in the United States to address the void in advanced wound care, received a Medicare Part B reimbursement code in 2000, gained inclusion in the diabetic foot ulcer guidelines from the Tucson Expert Consensus Conference in 2004 and recorded worldwide revenue of $1.4 billion from the V.A.C. in 2010.

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

Developing and commercializing new products is highly competitive. The market is characterized by extensive research and clinical efforts and rapid technological change. We face intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major pharmaceutical companies. We may be unable to respond to technological advances through the development and introduction of new products. Most of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources. These competitors 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.

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Regulatory Matters

FDA Regulation

Each of our products must be cleared or approved by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our product candidates are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products.

In the United States, the FDA subjects medical products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products, and we may be criminally prosecuted. Failure to comply with the law could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension or withdrawal of product approval, injunctions, or criminal prosecution.

The FDA has determined that our technology and product candidates constitute medical devices. The FDA determines what center or centers within the FDA will review the product and its indication for use, and also determines under what legal authority the product will be reviewed. For the current indications, our product candidate is being reviewed by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case the governmental review requirements would vary in some respects.

FDA Approval or Clearance of Medical Devices

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

Class I: general controls, such as labeling and adherence to quality system regulations;

Class II: special controls, pre-market notification (510(k)), specific controls such as performance standards, patient registries, and postmarket surveillance, and additional controls such as labeling and adherence to quality system regulations; and

Class III: special controls and approval of a pre-market approval (PMA) application.

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

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device, has the same intended use, and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than does a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product

modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then 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.

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

Obtaining medical device clearance, approval, or licensing in the United States or abroad can be an expensive process. The fees for submitting an original PMA to the FDA for consideration of device approval are substantial. Fees for supplement PMA s are less costly but still can be substantial. International fee structures vary from minimal to substantial, depending on the country. In addition, we are subject to annual establishment registration fees in the United States and abroad. Device licenses require periodic renewal with associated fees as well. In the United States, there is an annual requirement for submitting device reports for Class III/PMA devices, along with an associated fee. Currently, we are registered as a Small Business Manufacturer with the FDA and as such this places us in a reduced fee structure. As future revenues exceed a certain annual threshold limit, we may not qualify for the Small Business Manufacturer reduced fee structure and will be required to pay full fee amounts.

Clinical Trials of Medical Devices

One or more clinical trials are almost always required to support a PMA application and are sometimes required to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board (the IRB) has approved the study.

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

Post-Approval Regulation of Medical Devices

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

- the FDA Quality Systems Regulation (QSR), which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;

- labeling and claims regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and

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

We continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as do our suppliers, contract manufacturers, and contract testing laboratories.

International sales of medical devices manufactured in the United States that are not approved or cleared by the FDA are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Exported devices may also fall under the jurisdiction of the United States Department of Commerce/Bureau of Industry and Security and compliance with export regulations may be required for certain countries.

Manufacturing cGMP Requirements

If and when we manufacture medical devices, we will be required to comply with applicable FDA manufacturing requirements contained in the FDA s current good manufacturing practices (the cGMP) set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-PMA approval inspection before we can use them. We and some of our third party service providers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

The primary regulatory body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have an ISO 13485:2003 certification, as well as meet additional requirements of Canadian laws. We currently have this certification and will need to maintain it in order to have the potential to gain approval of a product candidate in Canada. We obtained a device license for dermaPACE from Health Canada in 2010 for the indication of devices for application of shock waves (pulsed acoustic waves) on acute and chronic defects of the skin and subcutaneous soft tissue .

The primary regulatory environment in Europe is the European Union, which consists of 25 member states and 42 competent authorities encompassing most of the major countries in Europe. In the European Union, the European Medicines Agency (EMA) and the European Union Commission have determined that dermaPACE, orthoPACE, Ossatron and Evotron will be regulated as medical device products. These devices have been determined to be Class IIb devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area.

The primary regulatory bodies and paths in Asia and Australia are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485.

European Good Manufacturing Practices

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

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

United States Anti-Kickback and False Claims Laws

In the United States, there are Federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to

civil and criminal penalties, including exclusion from participation in Federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. Other provisions of 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. In addition, certain states have implemented regulations requiring medical device and pharmaceutical companies to report all gifts and payments over $50 to medical practitioners. This does not apply to instances involving clinical trials. Although we intend to structure our future business relationships with clinical investigators and purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by Federal or state enforcement officials under these laws.

Third Party Reimbursement

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers compensation plans. These third party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse 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.

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

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

The initial phase of establishing a billing code for a medical service typically includes applying for a Category III Current Procedural Terminology (CPT) code. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as American Medical Association (AMA) CPT Editorial Panel review. A new Category III CPT code will be assigned if the AMA CPT Editorial Panel committee deems it meets criteria and is appropriate. The secondary phase in the CPT billing code process includes the establishment of a Category I CPT code in which relative value is analyzed and established by the AMA. The approval of this code, among other criteria, is based on widespread usage and established clinical efficacy of the medical service.

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.

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Environmental and Occupational Safety and Health Regulations

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

Milestone and Royalty Payments

Under an agreement with Sci-Do AG, an Austrian company from which we purchased certain patents, we are required to make various milestone and royalty payments based on the occurrence of certain events. Pursuant to the terms of the agreement, we are required to make a royalty payment of $100,000 upon FDA approval of our product for wound care. In addition, we are required to make royalty payments, based on a percentage of operating profit, for sales of FDA-approved wound care products in excess of $500,000 of earnings before interest and taxes. There were no payments under the agreement for the year ended December 31, 2010. During the year ended December 31, 2009, we paid $50,000 under the agreement.

Employees

As of May 5, 2011, we had a total of 29 employees in the United States. Of these 29 full-time employees, 12 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.

Properties

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

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

Legal Proceedings

Other than legal proceedings described below, 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.

HealthTronics, Inc., along with the Company, are defendants in an alleged breach of contract lawsuit dated April 21, 2006 brought in the Miami-Dade County Circuit Court, Florida by a former limited partner of a former limited partnership of the Company, Bone & Joint Treatment Centers of America. Bone & Joint Treatment Centers of America, the plaintiff, is seeking greater than $3 million. HealthTronics, Inc. has been responsible for the defense of the lawsuit on behalf of the Company and believes the case is unfounded and is contesting the claims vigorously.

There are no material proceedings known to us, pending or contemplated, in which any of our directors, officers or affiliates or any of our principal security holders, or any associate of any of the foregoing, is a party or has an interest adverse to us.

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MANAGEMENT, EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE

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

Name	Age	Position Held
Christopher M. Cashman	43	President, Chief Executive Officer and Director Officer
Barry J. Jenkins	48	Chief Financial Officer
Thomas H. Robinson	52	Director
Kevin A. Richardson, II	42	Director
John F. Nemelka	44	Director

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

Barry J. Jenkins joined the Company as Chief Financial Officer in September of 2009 and joined SANUWAVE, Inc. as Chief Financial Officer in April of 2006. Prior to joining SANUWAVE, Inc., he served as Chief Financial Officer for the Benefit Services Division of Automatic Data Processing, Inc. from March of 2005 to April of 2006. Previously, he was the Chief Financial Officer of Snowden Pencer, Inc. from January of 2002 to November of 2004. Mr. Jenkins is a certified public accountant with 27 years of financial management experience and a cum laude graduate of Virginia Tech.

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

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

John F. Nemelka joined the Company as a member of the board of directors in October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Nemelka brings to our board of directors a diverse financial and operational experience. Since 2001, Mr. Nemelka has served as a managing principal of NightWatch Capital Advisors, LLC, an investment management firm. Mr. Nemelka is also interim Chief Executive

Officer and a member of the board of directors of SWK Holdings Corporation, a publicly traded holding company, formerly named KANA Software, Inc., a provider of customer service software solutions.

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Summary Compensation Table for Fiscal Years 2010 and 2009

The following table provides certain information for the fiscal years ended December 31, 2010 and 2009 concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2010 and 2009.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)[4]	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Christopher M. Cashman Chief Executive Officer and President (Principal Executive Officer)	2010	$350,000			$ 668,500[2]			$ 23,027	$1,041,527
	2009	$305,000			$1,463,957[2]			$ 20,012	$1,788,969
Barry J. Jenkins Chief Financial Officer	2010	$233,730			$ 384,371[3]			$ 22,689	$ 640,790
	2009	$222,600			$ 555,835[3]			$ 19,149	$ 797,584
Cornelius A. Hofman(1) Former Sole Officer and Director	2010								
	2009								

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

(2) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10. Mr. Cashman was granted 241,106 shares of restricted Common Stock on September 15, 2009. Mr. Cashman was granted options to purchase 44,527 shares of Common Stock at $2.92 per share and granted options to purchase 487,086 shares of commons stock at $5.25 per share on September 15, 2009. Mr. Cashman was granted options to purchase 350,000 shares of Common Stock at $2.00 per share on November 1, 2010.

(3) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10. Mr. Jenkins was granted 118,653 shares of restricted Common Stock on September 15, 2009. Mr. Jenkins was granted options to purchase 20,660 shares of Common Stock at $2.92 per share and granted options to purchase 121,722 shares of Common Stock at $5.25 per share on September 15, 2009. Mr. Jenkins was granted options to purchase 20,000 shares of Common Stock at $4.05 per share on January 29, 2010. Mr. Jenkins was granted options to purchase 175,000 shares of Common Stock at $2.00 per share on November 1, 2010.

(4) Includes health, dental, life and disability insurance premiums and employee 401(k) matching contributions.

Employment Agreements

Christopher M. Cashman

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

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

In addition, upon the execution of his employment agreement, Mr. Cashman was granted three supplemental options to purchase Common Stock. The terms of the supplemental options were amended on September 15, 2009. The first and second supplemental options each provided him with the right to purchase 139,167 shares of Common Stock and the third supplemental option provided him with the right to purchase 208,752 shares of Common Stock. The initial exercise price of the supplemental options is $2.92 per share. The first supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $8.76 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds three times the closing price as of the first date that the Common Stock was listed ($5.25), the first supplemental option will fully vest. In such an event, the exercise price of the first supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25). The second supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $17.53 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds six times the closing price as of the first date that the Common Stock was listed ($5.25), the second supplemental option will fully vest. In such an event, the exercise price of the second supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25). The third supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $26.29 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds nine times the closing price as of the first date that the Common Stock was listed ($5.25), the third supplemental option will fully vest. In such an event, the exercise price of the third supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

In addition, upon the execution of the first amendment to his employment agreement, Mr. Cashman was granted the right to receive annually shares of Common Stock equal to two and one-half times his annual base salary in effect on the date of execution of the first amendment. The shares vest in four equal installments on each twelve month anniversary of the date of grant, provided that the vesting may be accelerated upon the achievement of certain performance goals established by the board of directors. No restricted stock was issued to Mr. Cashman under this provision in 2010 or 2009.

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

Termination. Mr. Cashman s employment may be terminated by either party at any time and for any reason; provided that Mr. Cashman will be required to give the Company at least 30 days advance written notice of any resignation. If Mr. Cashman is terminated by the Company for cause or resigns without good reason, he will be entitled to receive his (1) base salary through the termination date, (2) any annual bonus earned, but unpaid as of the date of termination for the immediately preceding fiscal year, (3) reimbursement for certain unreimbursed business expenses, and (4) such employee benefits to which he may be entitled under the employee benefit plans of the Company. If Mr. Cashman is terminated by the Company without cause or resigns for good reason, he will be entitled to receive all of the above plus (1) subject to his compliance with certain other provisions of the employment

agreement related to non-competition and confidentiality and the execution of an effective release of claims, continued payment of the base salary until twelve months following the date of termination, and (2) continued coverage of him and his beneficiaries under the Company s health insurance programs for a period of up to twelve months.

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

Change of Control. In addition to any other termination benefits that Mr. Cashman may be entitled to receive, if a change of control (as defined below) occurs, then subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, Mr. Cashman will also be entitled to receive 100% accelerated vesting of his options. Effective as of the first anniversary of the Merger, Mr. Cashman s right to receive the above change of control termination benefits will no longer be subject to his compliance with the non-compete provisions of his employment agreement. A change in control is defined in the employment agreement as the occurrence of any of the following events: (1) the sale, exchange, lease or other disposition of all or substantially all of the assets of the Company to a person (other than Prides Capital or NightWatch Capital) that will continue the business of the Company in the future; (2) a merger or consolidation involving the Company in which the voting securities of the Company owned by the shareholders of the Company immediately prior to such merger or consolidation do not represent, after conversion if applicable, more than 50% of the total voting power of the surviving controlling entity outstanding immediately after such merger or consolidation; or (3) any person (other than Prides Capital or NightWatch Capital) is or becomes the beneficial owner, directly or indirectly, of more than 50% of the total voting power of the voting stock of the Company and the representatives of Prides Capital and NightWatch Capital cease to have the ability to elect a majority of the board of directors.

Barry J. Jenkins

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

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

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

supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25). The third supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $26.29 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds nine times the closing price as of the first date that the Common Stock was listed ($5.25), the third supplemental option will fully vest. In such an event, the exercise price of the third supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

Termination. Mr. Jenkins employment may be terminated by either party at any time and for any reason; provided that Mr. Jenkins will be required to give the Company at least 30 days advance written notice of any resignation. If Mr. Jenkins is terminated by the Company for cause or resigns without good reason, he will be entitled to receive his (1) base salary through the termination date, (2) any annual bonus earned, but unpaid as of the date of termination for the immediately preceding fiscal year, (3) reimbursement for certain unreimbursed business

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

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

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc. s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. (the 2006 Plan). On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the Amended Plan). The Amended Plan permits grants of awards to selected employees and directors of the Company in the form of restricted stock or options to purchase shares of Common Stock. Options granted may include nonstatutory options as well as qualified incentive stock options. The Amended Plan is currently administered by the board of directors of the Company. The Amended Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Amended Plan are nonstatutory options which vest over a period of up to four years, and have a ten year term. The options are granted at an exercise price equal to the fair market value of the Common Stock on the date of the grant which is approved by the board of directors of the Company. The Amended Plan has 5,000,000 shares of Common Stock reserved for grant.

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

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

On December 31, 2010, there were 3,695,649 shares of Common Stock available for grant under the Amended Plan. For the year ended December 31, 2010, there were 545,000 options granted to the Company s executive officers under the Amended Plan. No options were granted to the Company s executive officers during the year ended December 31, 2009, under the 2006 Plan.

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Outstanding Equity Awards at 2010 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2010.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Christopher M. Cashman	723,600			$ 2.92	12/19/2015				
		139,167(1)		$ 2.92/$5.25	12/19/2015				
		139,167(2)		$ 2.92/$5.25	12/19/2015				
		208,752(3)		$ 2.92/$5.25	12/19/2015				
	350,000			$ 2.00	11/01/2020				
Barry J. Jenkins	356,037			$ 2.92	10/24/2016				
		34,778(4)		$ 2.92/$5.25	10/24/2016				
		34,778(5)		$ 2.92/$5.25	10/24/2016				
		52,166(6)		$ 2.92/$5.25	10/24/2016				
		20,000(7)		$ 4.05	01/29/2020				
	175,000			$ 2.00	11/01/2020				

(1) The supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $8.76 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds three times the closing price as of the first date that the Common Stock was listed ($5.25), the first supplemental option will fully vest. In such an event, the exercise price of the first supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

(2) The supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $17.53 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds six times the closing price as of the first date that the Common Stock was listed ($5.25), the second supplemental option will fully vest. In such an event, the exercise price of the second supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

(3) The supplemental option will fully vest on the earlier of (i) December 19, 2011, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $26.29 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds nine times the closing price as of the first date that the Common Stock was listed ($5.25), the third supplemental option will fully vest. In such an event, the exercise price of the third supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

(4) The supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $8.76 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $8.76 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds three times the closing price as of the first date that the Common Stock was listed ($5.25), the first supplemental option will fully vest. In such an event, the exercise price of the first supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

(5) The supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $17.53 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $17.53 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds six times the closing price as of the first date that the Common Stock was listed ($5.25), the second supplemental option will fully vest. In such an event, the exercise price of the second supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

(6) The supplemental option will fully vest on the earlier of (i) April 10, 2012, and (ii) the date that the Company or its shareholders (A) enters into a transaction that establishes a value for the Company on a per share basis equal to at least $26.29 per share, or (B) receives a valuation that establishes a value for the Company on a per share basis equal to at least $26.29 per share. Notwithstanding the above, if the Common Stock closing price equals or exceeds nine times the closing price as of the first date that the Common Stock was listed ($5.25), the third supplemental option will fully vest. In such an event, the exercise price of the third supplemental option will adjust to be the closing price of the Common Stock on the first date that the Common Stock was listed ($5.25).

(7) The options were granted January 29, 2010 and 5,000 options vest annually on January 29, 2011, 2012, 2013 and 2014, respectively.

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Director Compensation Table for Fiscal 2010

The following table provides certain information concerning compensation for each director during the fiscal year ended December 31, 2010.

Name[1]	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Thomas H. Robinson							
Kevin A. Richardson, II			$22,080				$22,080
John F. Nemelka			$22,080				$22,080

(1) Christopher M. Cashman, who is a member of our board of directors, has been omitted from this table since he received no compensation for serving on our board of directors.

(2) The following are the aggregate number of option awards outstanding that have been granted to each of our nonemployee directors as of December 31, 2010: Mr. Robinson 15,000; Mr. Richardson 15,000; and Mr. Nemelka 15,000.

Discussion of Director Compensation

The Company did not pay any director cash compensation for serving on our board of directors during the fiscal years ended December 31, 2010 or 2009. The Company may begin to compensate its directors in cash at some time in the future. On November 1, 2010, the Company issued options to purchase the Company s Common Stock at $2.00 per share to certain non-employee directors as follows: options to purchase 5,000 shares to Kevin A. Richardson, II and options to purchase 5,000 shares to John F. Nemelka. The options were vested when granted and expire ten years after the date of the grant. On January 29, 2010, the Company issued options to purchase the Company s Common Stock at $4.05 per share to certain non-employee directors as follows: options to purchase 5,000 shares to Kevin A. Richardson, II and options to purchase 5,000 to John F. Nemelka. The options are vested equally over a four year period and expire ten years after the date of the grant.

Disclosure of Commission Position on Indemnification of Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information, as of May 5, 2011, with respect to the beneficial ownership of the Company s outstanding Common Stock by (i) any holder of more than five percent, (ii) each of the Company s executive officers and directors, and (iii) the Company s directors and executive officers as a group.

Name of Beneficial Owner[1]	Number of Shares Beneficially Owned[2]	Percent of Shares Outstanding
Christopher M. Cashman [3]	1,411,673	6.4%
Barry J. Jenkins [4]	693,287	3.2%
Kevin A. Richardson, II [5]	2,892,258	12.9%
Thomas H. Robinson	15,000	*
John F. Nemelka	11,750	*
David N. Nemelka [6]	3,390,537	15.1%
Prides Capital Fund I, LP [7]	10,520,077	47.1%
NightWatch Capital Partners II, LP [8]	2,108,369	10.0%
All directors and executive officers as a group (5 persons)	5,023,968	20.9%

* Less than 1% of outstanding shares.

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

(2) Beneficial ownership includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of May 5, 2011. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, referred to in this current report as the Exchange Act. Pursuant to the rules of the Securities and Exchange Commission, referenced to in this current report as the SEC, certain shares of our Common Stock that a beneficial owner has the right to acquire within 60 days pursuant to the exercise of stock options or warrants are deemed to be outstanding for the purpose of computing the percentage ownership of such owner, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

(3) Includes options to purchase up to 1,073,600 shares of Common Stock and warrants to purchase up to 8,816 shares of Common Stock.

(4) Includes options to purchase up to 536,037 shares of Common Stock and warrants to purchase up to 3,508 shares of Common Stock.

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

(6) Based solely on information contained in filings made on schedule 13D, as amended, with the securities and exchange commission by the reporting person. Includes warrants to purchase up to 1,566,014 shares of Common Stock. The principal address of David N. Nemelka is 2662 Stonebury Loop Road, Springville, UT 84663.

(7)

Based solely on information contained in filings made on schedule 13D, as amended, with the securities and exchange commission by the reporting person. Includes warrants to purchase 1,438,088 shares of Common Stock. The principal business address of Prides Capital Fund, I, LP is 200 State Street, 13th floor, Boston, MA 02109.

(8) Based solely on information contained in filings made on schedule 13D, as amended, with the securities and exchange commission by the reporting person. Includes warrants to purchase 204,224 shares of Common Stock. The principal business address of NightWatch Capital Partners II, LP is 5314 River Run Drive, Suite 350, Provo, UT 84604.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Party Transactions

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

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

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Capital Fund I, LP. John F. Nemelka, who is a member of our board of directors, serves as managing principal of NightWatch Capital Advisors, LLC, an affiliate of NightWatch Capital Partners II, LP.

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

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

During 2010, we issued promissory notes totaling $1,750,000 to Kevin A. Richardson, II, our chairman of the board of directors, and $500,000 to David N. Nemelka, the brother of John F. Nemelka, a member our board of directors. On October 12, 2010, in conjunction with an offering, we amended the terms of the outstanding promissory notes such that the unpaid principal and interest on each note was exchanged into units (as described in the Liquidity and Capital Resources section). The unpaid principal and interest on the notes to Kevin A. Richardson, II totaled $1,790,504, and this sum was exchanged into a total of 895,252 units which consisted of 895,252 shares of Common Stock, 895,252 Class D warrants and 895,252 options, which, as amended, expire on January 31, 2011, to purchase another unit at the purchase price of $2.00 per unit. The unpaid principal and interest on the notes to David N. Nemelka totaled $522,504, and this sum was exchanged into a total of 261,252 units which consisted of 261,252 shares of Common Stock, 261,252 Class D warrants and 261,252 options, which, as amended, expire on January 31, 2011, to purchase another unit at the purchase price of $2.00 per unit.

Director Independence

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

SELLING STOCKHOLDERS

April 2011 Private Placement

On April 8, 2011, we completed a private placement to 28 institutional and individual accredited investors of 2,804,593 shares of our Common Stock at a purchase price of $3.25 per share for gross proceeds of $9,114,927. The net proceeds received by the Company were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of our Common Stock at an initial exercise price of $4.00 per warrant. For each of the warrants, the holder will be able to exercise the warrant on a cashless basis at any time following the one-year anniversary of the closing of the private placement, if a registration statement covering the shares of our Common Stock underlying such warrants is not effective. The net proceeds from the private placement, following the payment of offering-related expenses, are being used by us for working capital and other general corporate purposes.

At the closing of the private placement, we paid Rodman & Renshaw LLC, the placement agent for the private placement, cash compensation based on the gross proceeds of the private placement and a five-year warrant to purchase up to 93,080 shares of our Common Stock at an initial exercise price of $4.00 per warrant. The terms of the placement agent s warrants are identical to the warrants issued to investors in the private placement.

We have agreed, pursuant to the terms of a registration rights agreement with the investors in the private placement, to (i) file a registration statement with respect to the resale of the shares of our Common Stock sold to the investors and shares of our Common Stock issuable upon exercise of the warrants with the SEC on or before May 20,

2011; (ii) use our best efforts to have the registration statement declared effective by the SEC as soon as possible after the initial filing, and in any event no later than 30 days after the initial filing date (or 90 days in the event of a review of the registration statement by the SEC), and (iii) keep this the registration statement effective until all registrable securities may be sold under Rule 144 under the Securities Act. If we are unable to comply with any of the above covenants, we will be required to pay liquidated damages to the investors in the amount of 2.0% of the investors purchase price per month during such

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non-compliance (capped at a maximum of 12% of the purchase price), with such liquidated damages payable in cash.

The investors agreed, pursuant to the securities purchase agreement, not to engage in any short sales (as defined in the agreement) until the earlier of the effective date of the registration statement or the date when the shares of our Common Stock sold to the investors and shares of our Common Stock issuable upon exercise of the warrants are eligible for sale under Rule 144 under the Securities Act. We also agreed to certain restrictions on our ability to sell our equity securities until 60 days after the effective date of the registration statement.

The shares of our Common Stock and warrants issued in the private placement were exempt from registration under Section 4(2) of the Securities Act as a sale by an issuer not involving a public offering or under Regulation D promulgated pursuant to the Securities Act. None of the shares of Common Stock or warrants, or shares of our Common Stock underlying such warrants, were registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempts transactions by an issuer not involving any public offering. Such securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements and certificates evidencing such shares contain a legend stating the same.

Selling Stockholder Table

The following table sets forth:

- the name of the selling stockholders,
- the number of shares of Common Stock beneficially owned by the selling stockholders as of May 5, 2011,
- the maximum number of shares of Common Stock that may be offered for the account of the selling stockholders under this prospectus, and
- the amount and percentage of Common Stock that would be owned by the selling stockholders after completion of the offering, assuming a sale of all of the Common Stock that may be offered by this prospectus.

Except as noted below and elsewhere in this prospectus, the selling stockholders have not, within the past three years, had any position, office or other material relationship with us.

David N. Nemelka, one of the selling stockholders, is the brother of John F. Nemelka, who is a member of our board of directors.

Beneficial ownership is determined under the rules of the SEC. The number of shares beneficially owned by a person includes shares of Common Stock underlying warrants, stock options and other derivative securities to acquire our Common Stock held by that person that are currently exercisable or convertible within 60 days after May 5, 2011. The shares issuable under these securities are treated as outstanding for computing the percentage ownership of the person holding these securities, but are not treated as outstanding for the purposes of computing the percentage ownership of any other person.

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Name of Selling Stockholders (1)	Number of Shares Beneficially Owned Before Offering (2)	Amount of Shares of Common Stock Being Offered Pursuant to this Prospectus (3)	Shares Beneficially Owned After Offering Number (3)	Percentage (4)
Pacific Select Fund Health Sciences Portfolio (5)	270,766	270,766		*
Jennison Global Healthcare Master Fund, Ltd. (6)	307,700	307,700		*
Prudential Health Sciences Fund d/b/a Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc. (7)	1,575,380	1,575,380		*
Deerfield Special Situations Fund International Limited	562,154	562,154		*
Deerfield Special Situations Fund, LP	360,924	360,924		*
Investor Company f/b/o Rosalind Capital Partners L.P.	146,200	146,200		*
Investor Company f/b/o Rosalind Master Fund L.P.	161,600	161,600		*
DAFNA Lifescience Select Ltd	48,000	48,000		*
DAFNA Lifescience Ltd	24,000	24,000		*
DAFNA Lifescience Market Neutral Ltd	20,308	20,308		*
Alpha Capital Anstalt	153,846	153,846		*
Cranshire Capital LP (8)	61,540	61,540		*
Iroquois Master Fund Ltd	30,768	30,768		*
David N. Nemelka (9)	3,390,537	620,000	2,770,537	12.3%
McCollee Partners, LLC (10)	1,200,045	200,000	1,000,045	4.7%
Steven P. Zolman	252,688	186,000	66,688	*
Kelly Walker	214,032	124,000	90,032	*
Jared Chappell	157,344	124,000	33,344	*
Stacy Hall	112,050	62,000	50,050	*
KSP Investments, LLC	172,304	62,000	110,304	*
Ben E. Peay	310,859	62,000	248,859	1.2%
Craig A. Davis	82,700	62,000	20,700	*
Brian Trapnell	117,982	68,000	49,982	*
Hatty Investments, LLC	192,045	62,000	130,045	*
Michael Huish	112,011	62,000	50,011	*
Todd Pedersen	533,340	62,000	471,340	2.2%
Daniel Chen	91,900	68,000	23,900	*
Mark N. Schneider Trustee of the Mark N. Schneider Family Living Trust	99,797	62,000	37,797	*
Rodman & Renshaw LLC	93,080	93,080		*

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* Represents beneficial ownership of less than 1%.

(1) Unless otherwise noted, this table is based on information supplied to us by the selling stockholders and certain records of the Company.

(2) The share numbers in this column assumes the issuance of shares of Common Stock pursuant to the exercise of the outstanding warrants.

(3) The share numbers are based on records of the Company and information from the selling stockholders. The share numbers include Common Stock and shares of Common Stock issuable pursuant to the exercise of outstanding warrants held by the selling stockholders. We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders might not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares pursuant to this offering and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders.

(4) The percentage calculation after the offering is based on 20,907,536 shares of Common Stock outstanding and assumes the full exercise of outstanding warrants held by the Selling Stockholder on May 5, 2011.

(5) Number of shares being offered includes 135,383 shares of Common Stock issuable upon the exercise of warrants held by this selling stockholder. Jennison Associates LLC (Jennison) serves as sub-adviser with power to direct investments and/or power to vote the shares owned by this selling stockholder, as well as shares owned by certain other clients, and may be deemed to beneficially own the shares held by these entities. Jennison expressly disclaims ownership of such shares. Jennison is a wholly-owned subsidiary of Prudential Financial, Inc., which is a publicly-traded financial services company. The address of Jennison is 466 Lexington Avenue, New York, NY 10017. The selling stockholder is a mutual fund whose principal underwriter is an affiliated broker-dealer that is a member of the Financial Industry Regulatory Authority (FINRA). Jennison represents that it has purchased these shares in the ordinary course of business and, at the time of purchase, with no arrangement or understanding, directly or indirectly, with any person regarding the distribution of such shares.

(6) Number of shares being offered includes 153,850 shares of Common Stock issuable upon the exercise of warrants held by this selling stockholder. Jennison Associates LLC (Jennison) serves as investment manager with power to direct investments and/or power to vote the shares owned by this selling stockholder, as well as owned by certain other clients, and may be deemed to beneficially own the shares held by these entities. Jennison expressly disclaims ownership of such shares. Jennison is a wholly-owned subsidiary of Prudential Financial, Inc., which is a publicly-traded financial services company. The address of Jennison is 466 Lexington Avenue, New York, NY 10017. The selling stockholder is an exempted company incorporated under the laws of the Cayman Islands whose shares are distributed by an affiliated broker-dealer that is a member of the Financial Industry Regulatory Authority (FINRA). Jennison represents that it has purchased these shares in the ordinary course of business and, at the time of purchase, with no arrangement or understanding, directly or indirectly, with any person regarding the distribution of such shares.

(7) Number of shares being offered includes 787,690 shares of Common Stock issuable upon the exercise of warrants held by this selling stockholder. Jennison Associates LLC (Jennison) serves as sub-adviser with power to direct investments and/or power to vote the shares owned by this selling stockholder, as well as shares owned by certain other clients, and may be deemed to beneficially own the shares held by these entities. Jennison

expressly disclaims ownership of such shares. Jennison is a wholly-owned subsidiary of Prudential Financial, Inc., which is a publicly-traded financial services company. The address of Jennison is 466 Lexington Avenue, New York, NY 10017. The selling stockholder is a mutual fund whose principal underwriter is an affiliated broker-dealer that is a member of the Financial Industry Regulatory Authority (FINRA). Jennison represents that it has purchased these shares in the ordinary course of business and, at the time of purchase, with no arrangement or understanding, directly or indirectly, with any person regarding the distribution of such shares.

(8) Downsview Capital, Inc. (Downsview) is the general partner of Cranshire Capital, L.P. (Cranshire) and consequently has voting control and investment discretion over securities held by Cranshire. Mr. Mitchell P Koplin, President of Downsview, has voting control over Downsview. As a result of the foregoing, each of Mr. Koplin and Downsview may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the shares of Common Stock beneficially owned by Cranshire.

(9) As of the date hereof, Mr. David Nemelka beneficially owns 3,390,537 shares of Common Stock of the Issuer, including Common Stock issuable upon exercise of warrants to purchase 1,566,014 shares of Common Stock. This includes information contained in filings made on Schedule 13D, as amended, with the Commission by the reporting person. The principal address of David N. Nemelka is 2662 Stonebury Loop Road, Springville, UT 84663.

(10) Includes 50,015 shares of Common Stock, 50,015 Class A Warrants and 50,015 Class B Warrants owned by Mr. Keith Nellesen.

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Mr. Nellesen is manager of McColee Partners, LLC.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the OTC Bulletin Board or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities pursuant to Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by

them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling stockholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling stockholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale securities by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of securities of the Common Stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 55,000,000 shares, of which 50,000,000 shares are designated as Common Stock and 5,000,000 shares are designated as preferred stock. As of May 5, 2011, there were issued and outstanding:

- 20,907,536 shares of Common Stock,
- warrants to purchase 10,025,151 shares of Common Stock at a weighted average exercise price of $3.60 per share, and
- stock options to purchase 2,992,796 shares of Common Stock at a weighted average exercise price of $3.20 per share.

The following summary of the material provisions of our Common Stock, warrants, articles of incorporation and bylaws is qualified by reference to the provisions of our articles of incorporation and bylaws and the forms of warrant included or incorporated by reference as exhibits to the registration statement of which this prospectus is a part.

Common Stock

All shares of our Common Stock have equal voting rights and, when validly issued and outstanding, have one vote per share in all matters to be voted upon by the stockholders. Cumulative voting in the election of directors is not allowed, which means that the holders of more than 50% of the outstanding shares can elect all the directors if they choose to do so and, in such event, the holders of the remaining shares will not be able to elect any directors. The affirmative vote of a plurality of the shares of Common Stock voted at a stockholders meeting where a quorum is present is required to elect directors and to take other corporate actions. Holders of our Common Stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds. However, the current policy of our board of directors is to retain earnings, if any, for the operation and expansion of the Company. Upon liquidation, dissolution or winding-up, the holders of our Common Stock are entitled to share

ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities and the liquidation preference of any outstanding preferred stock. The holders of our Common Stock have no preemptive, subscription, redemption or conversion rights. All issued and outstanding shares of Common Stock are, and the Common Stock reserved for issuance upon exercise of our stock options and warrants will be, when issued, fully-paid and non-assessable.

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Preferred Stock

Our articles of incorporation authorize the issuance of up to 5,000,000 shares of blank check preferred stock with designations, rights and preferences as may be determined from time to time by our board of directors. No preferred shares are currently issued or outstanding.

Warrants

The following is a brief summary of material provisions of the warrants issued in the April 2011 private placement.

Exercise Price and Terms. Each warrant entitles the holder thereof to purchase at any time until April 8, 2016, at a price of $4.00 per share, subject to certain adjustments referred to below, shares of our Common Stock. The holder of any warrant may exercise such warrant by surrendering the warrant to us, with the notice of exercise properly completed and executed, together with payment of the exercise price. The warrants may also be exercised on a cashless-exercise basis by investors if a resale registration statement covering the shares underlying the warrants has not been declared effective by April 8, 2012. The warrants may be exercised at any time in whole or in part at the applicable exercise price until expiration of the warrants. No fractional shares will be issued upon the exercise of the warrants.

Adjustments. The exercise price and the number of shares of Common Stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of certain events, including stock dividends, stock splits, combinations or reclassifications of the Common Stock. Additionally, an adjustment would be made in the case of a reclassification or exchange of Common Stock, consolidation or merger of our Company with or into another corporation (other than a consolidation or merger in which we are the surviving corporation) or sale of all or substantially all of our assets in order to enable holders of the warrants to acquire the kind and number of shares of stock or other securities or property receivable in such event by a holder of the number of shares of Common Stock that might otherwise have been purchased upon the exercise of the warrant. No adjustment to the number of shares and exercise price of the shares subject to the warrants will be made for dividends (other than stock dividends), if any, paid on our Common Stock.

Transfer, Exchange and Exercise. The warrants may be presented to us for exchange or exercise at any time on or prior to April 8, 2016, at which time the warrants become wholly void and of no value. Prior to any transfer of the warrants the holder must notify us of the same and, if subsequently requested, provide a legal opinion regarding the transfer to us.

Warrantholder Not a Stockholder. The warrants do not confer upon holders any voting, dividend or other rights as a shareholder of our Company.

Trading Information

Our shares of Common Stock are currently quoted in the over-the-counter market on the OTC Bulletin Board. Our warrants will not be registered or listed for trading.

Transfer Agent

The transfer agent and registrar for our Common Stock is Action Stock Transfer Corp., 7069 S. Highland Drive, Suite 300, Salt Lake City, Utah 84121. We serve as warrant agent for the warrants.

SHARES AVAILABLE FOR FUTURE SALE

As of May 5, 2011, we had 20,907,536 shares of Common Stock outstanding, not including shares issuable upon the exercise of outstanding warrants, stock options and other convertible securities. All shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless they are purchased by our affiliates, as that term is defined in Rule 144 promulgated under the Securities Act.

The outstanding shares of our Common Stock not included in this prospectus will be available for sale in the public market as follows:

Public Float

Of our outstanding shares, 14,734,660 shares are beneficially owned by executive officers, directors and affiliates of the Company. The remaining 6,172,876 shares constitute our public float which, based on the last sale price of our Common Stock reported on the OTC Bulletin Board on May 5, 2011, equaled approximately $28,395,230.

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Rule 144

In general, under Rule 144, as currently in effect, a person who has beneficially owned shares of our Common Stock for at least six months, including the holding period of prior owners other than affiliates, is entitled to sell his or her shares without any volume limitations; an affiliate, however, can sell such number of shares within any three-month period as does not exceed the greater of:

- 1% of the number of shares of our Common Stock then outstanding, which equaled 209,075 shares as of May 5, 2011, or
- the average weekly trading volume of our Common Stock, assuming our shares are then traded on a national securities exchange, during