SANUWAVE Health, Inc.
Form S-1
March 29, 2013

As filed with the Securities and Exchange Commission on March 29, 2013
Registration No. 333-_____

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

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITES 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.)

11475 Great Oaks Way, Suite 150
Alpharetta, Georgia 30022
(770) 419-7525

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Joseph Chiarelli
Chief Executive Officer
SANUWAVE Health, Inc.
11475 Great Oaks Way, Suite 150
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, 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: x

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	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered (1)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Units, each unit consisting of one share of Common Stock, $0.001 par value, and a warrant to purchase up to an additional share of Common Stock	$ 6,000,000	$ 818.40
Common Stock included in the Units	$ -	$ -
Warrants included in the Units	$ -	(3)
Common Stock issuable upon exercise of the warrants included in the Units	$ -	(3)
Total	$ 6,000,000	$ 818.40

(1) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(2) Calculated pursuant to Rule 457(o) under the Securities Act on the basis of the maximum aggregate offering price of the securities being registered.

(3) No Registration Fee required pursuant to Rule 457(g).

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.

The information in this prospectus is not complete and may be changed. We may not sell these securities described herein until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary 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.

Preliminary Prospectus, Subject to Completion, Dated March 29, 2013

Up to $6,000,000 of Units, each Unit consisting of one share of common stock and a warrant to purchase up to an additional _____ share of common stock

We are offering up to _____ Units at a purchase price of $____ per Unit, with each Unit consisting of one share of our common stock and a warrant to purchase up to an additional _____ share of our common stock at an exercise price of $_____ per share. The Units will separate immediately and the common stock and warrants will be issued separately. We are not required to sell any specific dollar amount or number of Units, but will use our best efforts to sell all of the Units being offered. The offering expires on the earlier of (i) the date upon which all of the Units being offered have been sold, or (ii) _____, 2013. In addition, we may terminate the offering at any time prior to the expiration date. All costs associated with the registration will be borne by us.

Our common stock is quoted on the OTC Bulletin Board under the symbol “SNWV”. The last reported sale price of our common stock on March 28, 2013 on the OTC Bulletin Board was $0.91 per share. There is no established trading market for the warrants.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 5 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Brokers or dealers effecting transactions in these securities should confirm that the securities are registered under the applicable state law or that an exemption from registration is available.

The date of this prospectus is _____, 2013

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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.

Unless the context requires otherwise, the words ‘‘SANUWAVE,’’ ‘‘we,’’ ‘‘Company,’’ ‘‘us,’’ and ‘‘our’’ in this prospectus SANUWAVE Health, Inc. and our wholly-owned subsidiary SANUWAVE, Inc.

About This Prospectus

You may rely only on the information contained in this prospectus or that we have referred you to. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

Our Company

We are a shockwave technology company using noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to solicit a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which is in a supplemental Phase III clinical study with possible FDA approval in 2015 subject to submission of satisfactory clinical study results.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. We currently are not marketing any commercial products in the United States. We generate our revenues from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada and Asia/Pacific.

In addition, we believe there are significant license/partnership opportunities for our shockwave technology in non-medical uses, including energy, food and industrial markets, and we believe we have a broad intellectual property portfolio and broad know-how.

Product Overview

dermaPACE – Our lead product candidate

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. We have identified and contracted with clinical study sites and are in the process of negotiating contracts with additional sites for participation in the clinical study. We

expect that patient enrollment will begin in the second quarter of 2013.

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Pulsed Acoustic Cellular Expression (PACE) Technology for regenerative medicine

We believe we have demonstrated that our technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron®, Evotron®, and orthoPACE® devices in Europe and Asia. Our lead product candidate for the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

We are focused on developing our Pulsed Acoustic Cellular Expression (PACE) technology to activate healing in:

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

Non-medical uses for our shockwave technology

In addition to healthcare uses, our high-energy, acoustic pressure shockwaves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. We intend to seek to exploit such potential uses through licensing and/or partnership opportunities.

Strategy

Our objective is to be a leader in the development and commercialization of our shockwave technology, which utilizes noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other non-medical applications. The key elements of our strategy include the following:

- Obtain FDA approval for our dermaPACE device to treat diabetic foot ulcers.

Our initial focus is obtaining FDA approval for our lead product candidate, dermaPACE, for the wound care market, initially in the United States for diabetic foot ulcers, which we believe represents a large, unmet need. The FDA has granted approval of our IDE Supplement to conduct a clinical trial utilizing the dermaPACE device in the treatment of diabetic foot ulcers. We have identified and entered into contracts with clinical study sites and are in the process of contracting with additional sites for participation in the clinical study. We expect patient enrollment to begin in the second quarter of 2013.

- Develop and commercialize our noninvasive biological response activating devices in the regenerative medicine area 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, plastic/cosmetic and cardiac indications, possibly through potential license and/or partnership arrangements.

- License and seek partnership opportunities for our non-medical shockwave technology platform, know-how and extensive patent portfolio.

We intend to use our shockwave technology and know-how for non-medical uses, including energy, food, water and industrial markets, through license/partnership opportunities.

- Support the global distribution of our products.

Our portfolio of products, the dermaPACE and orthoPACE, are CE Marked and sold through select distributors in certain countries in Europe, Canada and Asia/Pacific. Our revenues are from sales of the devices and related applicators in these markets. We currently do not market any commercial products in the United States. We intend to continue to add additional distribution partners in Europe and Asia/Pacific.

Trading Market

Our common stock is quoted on the Over-The-Counter Bulletin Board under the symbol “SNWV.OB.”

Corporate Information

We were incorporated in the State of Nevada on May 6, 2004, under the name Rub Music Enterprises, Inc. Our wholly-owned subsidiary, SANUWAVE, Inc., which we acquired in a reverse merger transaction in September 2009, was incorporated in the State of Delaware on July 21, 2005. In November 2009, we changed our name to SANUWAVE Health, Inc. Our principal executive offices are located at 11475 Great Oaks Way, Suite 150, Alpharetta, Georgia 30022, and our telephone number is (770) 419-7525. Our website address is www.sanuwave.com. The information on our website is not a part of this prospectus.

About this Offering

Securities being offered by us	_____ Units, each Unit consisting of one share of common stock and one warrant to purchase _____ share of common stock at an exercise price of $____ per share.

Offering price	$_____ per Unit.
Description of Warrants	The warrants will be exercisable at any time during the period commencing on the date of closing of the offering and ending on the fifth anniversary of the closing of offering at an exercise price per share equal to $_____.
Shares of common stock that may be issued upon the exercise of warrants issued as part of the Units	_____ shares of common stock
Use of proceeds	We intend to use the net proceeds from the sale of shares by us primarily for expenses related to our dermaPACE clinical trial for treating diabetic foot ulcers in the United States and for other general corporate purposes. However, we have outstanding an aggregate $2,067,500 in principal and accrued interest on our 18% Senior Secured Convertible Promissory Notes (Senior Secured Notes), which begin to mature in May 2013. We plan to have such notes amended prior to commencement of the offering, such that subject to the condition that we raise at least $4,000,000 in gross proceeds through this offering, the Senior Secured Notes will automatically convert into (i) common stock at a conversion price of $0.20, and (ii) warrants to purchase the number of shares of common stock equal to the number of shares such holder would have received if it had invested in the offering an amount equal to the principal and interest on the note being converted. If we do not raise at least $4,000,000 in gross proceeds through this offering the Senior Secured Notes will not automatically convert to common stock and they will become due and payable and we will use all or part of any net proceeds towards repayment of the Senior Secured Notes. See “Use of Proceeds” and “Description of Securities”.
Expiration time/date	_____, 2013
Common stock outstanding: Before the offering	21,580,536 shares
After the offering	_____ shares
OTC Bulletin Board market symbol	SNWV
Risk factors	See “Risk Factors” beginning on page 5 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.

The number of shares of our common stock to be outstanding after completion of this offering is based on 21,580,536 shares outstanding as of March 25, 2013 and assumes the sale of all Units offered in this offering, but does not include any shares issuable upon exercise of the warrants offered. The number of shares shown to be outstanding does not include shares reserved for issuance upon the (i) exercise of outstanding warrants to purchase 7,789,991 shares of common stock with a weighted average exercise price of $3.63, (ii) exercise of outstanding options to purchase 8,604,330 shares of common stock with a weighted average exercise price of $1.14, or (iii) conversion of outstanding convertible notes in the aggregate amount of $2,067,500, convertible into 10,337,500 shares of common stock at a weighted average conversion price of $0.20.

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, 2012	December 31, 2011
Consolidated Statement of Operations Data		
Revenues	$769,217	$802,572
Net loss	$(6,401,494)	$(10,238,797)
Weighted average shares outstanding	20,915,869	19,624,061
Net loss per share - basic and diluted	$(0.30)	$(0.52)
Consolidated Balance Sheet Data (at end of period)		
Working capital (deficit)	$(2,413,536)	$2,256,970
Total assets	$1,850,536	$6,166,224
Total liabilities	$8,369,541	$7,702,701
Total stockholders' deficit	$(6,519,005)	$(1,536,477)

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

Our auditors have raised substantial doubts as to our ability to continue as a going concern.

Our financial statements have been prepared assuming we will continue as a going concern. Since our inception, we have experienced recurring losses from operations. As of December 31, 2012, we have an accumulated deficit of $70,910,322. We generate only minimal revenues and we continue to experience operating losses. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. We anticipate that our operating expenses will continue to increase and we will continue to incur substantial losses in future periods unless and until we are successful in significantly increasing our revenues and cash flow. There are no assurances that we will be able to increase our revenues and cash flow to a level which supports profitable operations and provides sufficient funds to pay our obligations. If we are unable to meet those obligations, we could be forced to cease operations in which event investors would lose their entire investment in our Company.

We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so, and/or the terms of any financings may not be advantageous to us.

The continuation of our business is dependent upon raising additional capital. As of December 31, 2012, we had cash and cash equivalents of $70,325 and negative working capital of $2,413,536. For the years ended December 31, 2012 and 2011, our net cash used by operating activities was $4,290,121 and $8,831,699, respectively. We need additional financial support which may include: raising additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, an investment by a strategic partner in a specific clinical indication or market opportunity; or selling all or a portion of our assets. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

Even if we sell all of the Units offered in this offering, we will require additional capital to support development and continue our operations in the near future. We estimate that, if we sell all of the Units offered, we will require additional funds to continue operations. Such additional capital may not be available on terms that are favorable to us, if at all. If we are unable to raise such additional funds, we may be forced to cease operations.

We have no long-term credit facility or other source of long-term funding. Our Senior Secured Notes are secured by all our assets and begin to mature in May 2013. If we are unable to raise a minimum of $4,000,000 in this offering such that these notes automatically convert to common stock, or if we are unable to successfully raise other additional capital, the note holders could demand payment.

We have no long-term credit facility or other source of long-term funding. The continuation of our business is dependent upon raising additional capital. On March 8, 2013, we completed a private placement of an aggregate of $2,000,000 of our Senior Secured Notes, which begin to mature in May 2013.

Prior to commencement of the offering, we intend to have the Senior Secured Notes amended such that they will automatically convert into common stock if we raise $4,000,000 or more through a qualified financing (such as this offering) and/or license agreement as defined in the Senior Secured Note agreements. If we do not raise at least $4,000,000, the Senior Secured Notes will not automatically convert to common stock and they will become due and payable upon maturity, beginning in May 2013. In the event that we raise, in this offering, less than $4,000,000, then we may need to use the net proceeds to repay these notes. Any such actions could adversely affect our financial condition and the value of our common stock.

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

For the year ended December 31, 2012, we had a net loss of $6,401,494 and used $4,290,121 of cash in operations. As of December 31, 2012, we had an accumulated deficit of $70,910,322 and a total stockholders' deficit of $6,519,005. As a result of our significant research, clinical development, regulatory compliance and general and administrative expenses, we expect to incur losses for at least the next several years as we continue to incur expenses related to seeking FDA approval for our dermaPACE device. 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.

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

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

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

- unforeseen developments during our 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;
- 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.

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.

We are no longer able to rely on Prides Capital Partners, LLC and NightWatch Capital LLC for financial support, and as a result must 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 unrelated 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.

Current economic conditions could adversely affect our operations.

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

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

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

Our product candidates may not be developed or commercialized successfully.

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

We are subject to the risks that:

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

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

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

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

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

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

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

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

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

We may not successfully establish and maintain licensing and/or partnership arrangements for our technology for non-medical uses, which could adversely affect our ability to develop and commercialize our non-medical technology.

Our strategy for the development, testing, manufacturing and commercialization of our technology for non-medical uses generally relies on establishing and maintaining collaborations with licensors and other third parties. We may not be able to obtain, maintain or expand these or other licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to obtain, maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to obtain, maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our technology for non-medical uses.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our technology for non-medical uses, including possibly the design and manufacture of product materials, potentially the obtaining of regulatory approvals and the marketing and distribution of any successfully developed products. Our collaborators also may have or acquire rights to control aspects of our product development programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we may contemplate. In addition, if any of these collaborators withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

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

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

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

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

As a small company with 11 employees, our success depends on the continuing contributions of our management team and qualified personnel. Our success depends in large part on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical, biotechnology and medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

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

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

Regulatory Risks

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

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

- the product candidate may not prove to be safe or effective;
- the product candidate's benefits may not outweigh its risks;
- the results from advanced clinical trials may not confirm the positive results from pre-clinical studies and early clinical trials;

- the FDA or comparable foreign regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than us; and
- the FDA or other regulatory agencies may require additional or expanded trials and data.

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

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected. The FDA has determined that our technology and product candidates constitute "medical devices", and are thus subject to review by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case applicable governmental review requirements could vary in some respects and be more lengthy and costly.

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

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

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

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

We are also subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, 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 and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

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

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

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

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

We will rely on third parties to conduct our dermaPACE clinical trial, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.

We have engaged a clinical research organization (CRO) and other third party vendors to assist in the conduct of our clinical trial for dermaPACE. There are numerous sources that are capable of providing these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our dermaPACE clinical trial, the commercial prospects for the product could be harmed and our ability to generate product revenue would be delayed or prevented. Any failure of our CRO to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our product and obtain regulatory approval. Problems with the timeliness or quality of the work of our CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our clinical trial, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trial in an acceptable manner and at an acceptable cost.

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

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

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

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

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

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

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

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

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

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

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, beginning in 2013;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on device manufacturers for any “transfer of value” made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests, with the first of such reports due March 31, 2013 for calendar year 2012;
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, beginning on or before January 1, 2013;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biological products that are demonstrated to be biosimilar or interchangeable with a licensed biological product.

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

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

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

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

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

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

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

The medical device industry is subject to substantial regulation by the FDA and by comparable international agencies. In addition to requiring clearance or approval to market new or improved devices, we are subject to ongoing regulation as a device manufacturer. Governmental regulations cover many aspects of our operations, including quality systems, marketing and device reporting. As a result, we continually collect and analyze information about our product quality and product performance through field observations, customer feedback and other quality metrics. If we fail to comply with applicable regulations or if post market safety issues arise, we could be subject to enforcement sanctions, our promotional practices may be restricted, and our marketed products could be subject to recall or otherwise impacted. Each of these potential actions could result in a material adverse effect on our business, operating results and financial condition.

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

We conduct research and development and manufacturing operations in our facility. Our research and development process may, at times, involve the controlled use of hazardous materials and chemicals. We 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.

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We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

Regulatory approval of our product candidates may be withdrawn at any time.

After regulatory approval has been obtained for medical device products, the product and the manufacturer are subject to continual review, including the review of adverse experiences and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions, or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturing facilities we use to make any of our products will also be subject to periodic review and inspection by the FDA or other regulatory authorities, as applicable. The discovery of any new or previously unknown problems with the product or facility may result in restrictions on the product or facility, including withdrawal of the product from the market. We will continue to be subject to the FDA or other regulatory authority requirements, as applicable, governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our product candidates, even those that the FDA or other regulatory authority, as applicable, had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

Risks Related to Intellectual Property

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

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

- obtain and/or maintain protection for our product candidates under the patent laws of the United States and other countries;

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

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

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

In particular, we cannot assure you that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Units and This Offering

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to (i) the sale by us of up to_____ shares offered in this offering at a public offering price of $____ per share; (ii) the conversion of our 18% Senior Secured Convertible Promissory Notes, in the principal amount of $_____, including accrued interest, at a conversion price of $0.20 per share; and (iii) and (iii) after deducting the estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $___ per share, or___ %, at the public offering price.

In addition, in the past, we issued options and warrants to acquire shares of common stock, and warrants are being issued to investors in this offering and holders of the Senior Secured Notes. To the extent these options or warrants are ultimately exercised, you will sustain future dilution.

There is no minimum amount required to be raised in the offering, and if we cannot raise sufficient funds from this offering, we may need to curtail or cease operations.

There is not a minimum amount of securities that need to be sold in this offering for us to access the funds. Therefore, the proceeds of this offering will be immediately available for use by us and we do not have to wait until a minimum number of shares have been sold to keep the proceeds from any sales. We cannot assure you that subscriptions for the entire offering will be obtained. We have the right to terminate this offering at any time, regardless of the number of securities we have sold since there is no minimum subscription requirement. Our ability to meet our financial obligations, cash needs, and to achieve our objectives, could be adversely affected if the entire offering is not fully subscribed and as a result we could be forced to curtail or cease our operations.

We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

Management will retain broad discretion over the use of the net proceeds of this offering. Stockholders may not agree with such uses, and our use of the proceeds may not yield a significant return or any return at all for our stockholders. We plan to use the net proceeds from this offering for the dermaPACE clinical trial in the United States, working capital and general corporate purposes. Because of the number and variability of factors that will determine our use of the proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could have a material and adverse effect on our business. For a further description of our intended use of the net proceeds of the offering, see “Use of Proceeds.”

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

As of March 25, 2013, Prides Capital owned 42.1% of our outstanding common stock and NightWatch Capital owned 8.8% of our outstanding common stock. In addition, Kevin A. Richardson, II, who is managing partner of Prides Capital, owns 6.7% of our outstanding common stock. Mr. Richardson was appointed by Prides Capital and John F. Nemelka was appointed by NightWatch Capital to serve on our board of directors. For as long as Prides Capital and NightWatch Capital own a majority of our shares of common stock, they will be able to control the election of all of the members of our board of directors and control the vote of shareholders on other matters. For as long as they own a significant percentage of our outstanding stock, even if less than a majority, Prides Capital and NightWatch Capital will be able to control and exercise significant influence over our business affairs, including the general strategic direction of our business, the incurrence of indebtedness by us, the issuance of any additional equity securities, the repurchase of equity securities and the payment of dividends, and will have the power to determine or significantly influence the outcome of matters submitted to a vote of our shareholders, including mergers, consolidations, sales or dispositions of assets, reductions in share capital, other business combinations and amendments to our articles of incorporation. Prides Capital and NightWatch Capital may take actions with which you do not agree, including actions that delay, defer or prevent a change in control of our company or that could adversely affect the market price of our common stock. In addition, they may take other actions that might be favorable to them, but not favorable to us or our other shareholders. Also, if either Prides Capital or NightWatch Capital sells all or a portion of its interest in us, it may cause the price of our common stock 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:

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

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

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

To date, there has been a limited trading market for our common stock and we cannot predict how liquid the market for our common stock might become. Our common stock is quoted on the Over-the-Counter Bulletin Board (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 exists. The market price for our common stock is subject to volatility and holders of our common stock may be unable to resell their shares at or near their original purchase price, or at any price. In the absence of an active trading market:

- investors may have difficulty buying and selling, or obtaining market quotations for our common stock;
- market visibility for our common stock may be limited; and
- a lack of visibility for our common stock may have a depressive effect on the market for our common stock.

Trading for our common stock is limited under the SEC's penny stock regulations, which has an adverse effect on the liquidity of our common stock.

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

SEC regulations also require additional disclosure in connection with any trades involving a "penny stock," including the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and its associated risks. These requirements severely limit the liquidity of securities in the secondary market because only a few brokers or dealers are likely to undertake these compliance activities. Compliance with these requirements may make it more difficult for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market.

As an issuer of "penny stock", the protection provided by the federal securities laws relating to forward looking statements does not apply to us.

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. In addition, the Senior Secured Notes restrict us from paying a dividend as long as the notes are outstanding. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock

price appreciates.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our board of directors has the right, without stockholder approval, to issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the voting power and equity interest of the holders of common stock, which could be issued with the right to more than one vote per share, and could be utilized as a method of discouraging, delaying or preventing a change of control. The possible negative impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to issue any shares of preferred stock or to create any series of preferred stock, we may issue such shares in the future.

There is no trading market for the warrants being offering and as a result you may not be able to sell the warrants.

There is no market for the warrants being offered in this offering and there may never be a market for the warrants. In the absence of an active trading market, you may have difficulty buying and selling or obtaining market quotations; the market visibility for the warrants may be limited, and the lack of visibility for the warrants may have a depressive effect on the market price for the warrants.

The warrants are speculative in nature.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $_____ per share, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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. Statements in this prospectus that are not historical facts are hereby identified as ‘‘forward-looking statements’’. Forward-looking statements convey our current expectations or forecasts of future events. All statements in this prospectus, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding our future financial results, clinical trial results, regulatory approvals, operating results, business strategies, projected costs, products, competitive positions, management’s plans and objectives for future operations, and industry trends. These forward-looking statements are based on management’s estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as “may,” “will,” “should,” “could,” “would,” “expect,” “anticipate,” “believe,” “estimate,” “predict,” “potential” and “continue,” the negative of these terms, or other comparable terminology. These forward-looking statements include, among other things, statements about:

- timing of clinical studies and eventual FDA approval of dermaPACE and our other product candidates;
- regulatory actions that could adversely affect the price of or demand for our approved products;
- our intellectual property portfolio;
- market acceptance of and demand for dermaPACE and our product candidates;
- our marketing and manufacturing capacity and strategy;
- 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 U.S. Securities and Exchange Commission (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 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.
11475 Great Oaks Way, Suite 150
Alpharetta, Georgia 30022
Attention: Barry J. Jenkins, Chief Financial Officer and COO
Telephone: (770) 419-7525

USE OF PROCEEDS

We estimate that the net proceeds from the sale of Units by us, assuming the sale of all of the Units will be approximately $_____, after deducting estimated offering expenses payable by us, based upon an assumed public offering price of $_____ per Unit. However, this is a best efforts offering, with no minimum, and there can be no assurance that the offering will result in significant proceeds, or enough proceeds to continue to operate our business operations.

We estimate that the net proceeds from the sale of Units by us, assuming the sale of 50% of the Units will be approximately $_____, after deducting estimated offering expenses payable by us, based upon an assumed public offering price of $_____ per Unit.

We estimate that the net proceeds from the sale of Units by us, assuming the sale of 25% of the Units will be approximately $_____, after deducting estimated offering expenses payable by us, based upon an assumed public offering price of $_____ per Unit.

We intend to use the net proceeds from the sale of Units by us primarily for expenses related to our dermaPACE clinical trial for treating diabetic foot ulcers in the United States and for other general corporate purposes. However, we have outstanding an aggregate $2,067,500 in principal and accrued interest on our 18% Senior Secured Convertible Promissory Notes (Senior Secured Notes), which begin to mature in May 2013. Prior to commencement of this offering, we intend to have such notes amended such that, subject to the condition that we raise at least $4,000,000 in gross proceeds through this offering, the Senior Secured Notes will automatically convert into (i) common stock at a conversion price of $0.20, and (ii) warrants to purchase the number of shares of common stock equal to the number of shares such holder would have received if it had invested in the offering an amount equal to the principal and interest on the note being converted. Thus, if we do not raise at least $4,000,000 in gross proceeds through this offering the Senior Secured Notes will not automatically convert to common stock and they will become due and payable and we will use all or part of any net proceeds towards repayment of the Senior Secured Notes.

Therefore, if we fail to raise at least $4,000,000 in gross proceeds through this offering, we will need to use some or all any net proceeds we receive towards repayment of the Senior Secured Notes.

Until we use the net proceeds of this offering, we intend to invest the net proceeds in short-term, investment-grade securities. We cannot predict whether the proceeds invested will yield a favorable return.

PLAN OF DISTRIBUTION

Distribution

We are offering up to _____ Units at a purchase price of $____ per Unit, with each Unit consisting of one share of our common stock and a warrant to purchase up to an additional _____ share of our common stock at an exercise price of $_____ per share. The Units will separate immediately and the common stock and warrants will be issued separately and the common stock will trade separately.

We are offering the Units on a best efforts basis. This prospectus is part of a registration statement that permits our officers and directors to sell the Units directly to the public, with no commission or other remuneration payable to them for any Units that are sold by them. We may also engage registered broker-dealers to offer and sell Units. Subscriptions will be effective only on acceptance by us, and we reserve the right to reject any subscription in whole or in part. Subscribers must be provided a copy of this prospectus. We will send each investor a written confirmation of the acceptance of the investor's subscription for Units. We may terminate the offering at any time.

This offering expires at _____ on _____, 2013. The offering will terminate automatically prior to the expiration date, if the offering is fully subscribed. In addition, we may terminate the offering at any time prior to the expiration date. Because there is no minimum offering amount required as a condition to closing this offering, the actual public offering amount and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth herein.

Our obligations to issue and sell the securities offered hereby to the purchasers is subject to the conditions set forth in a securities purchase agreement, which may be waived by us at our discretion. A purchaser's obligation to purchase the securities is subject to the conditions set forth in a securities purchase agreement as well, which may also be waived by the purchaser.

Rule 3a4-1 sets forth those conditions under which a person associated with an issuer may participate in the offering of the issuer's securities and not be deemed to be a broker-dealer. Those conditions are as follows:

a. Our officers and directors are not subject to a statutory disqualification, as that term is defined in Section 3(a)(39) of the Act, at the time of their participation;

b. Our officers and directors will not be compensated in connection with their participation by the payment of commissions or other remuneration based either directly or indirectly on transactions in securities;

c. Our officers and directors are not, nor will they be at the time of their participation in the offering, an associated person of a broker-dealer; and

d. Our officers and directors meet the conditions of paragraph (a)(4)(ii) of Rule 3a4-1 of the Exchange Act, in that they (A) primarily perform, or intend primarily to perform at the end of the offering, substantial duties for or on behalf of our company, other than in connection with transactions in securities; and (B) are not a broker or dealer, or been associated person of a broker or dealer, within the preceding twelve months; and (C) have not participated in selling and offering securities for any Issuer more than once every twelve months other than in reliance on Paragraphs (a)(4)(i) and (a)(4)(iii).

Certain of our affiliates may purchase Units in this offering on the same terms as they are offered and sold to the public.

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses will be approximately $_____, all of which are payable by us.

Pricing of this Offering

The public offering price of the Units was determined by us. Factors considered in determining the prices and terms of the shares include:

- the history and prospects of companies in our industry;
- prior offerings of those companies;
- our prospects for developing and commercializing our products;
- our capital structure;
- an assessment of our management and their experience;
- general conditions of the securities markets at the time of the offering; and
- other factors as were deemed relevant.

Penny Stock

The SEC has adopted Rule 15g-9 which establishes the definition of a ”penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and

- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and

- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the ”penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock.

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.”

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

	Price Range	
	High	Low
2013		
First Quarter	$0.95	$ 0.16

	Price Range	
	High	Low
2012		
First Quarter	$0.53	$ 0.30
Second Quarter	$0.49	$ 0.24
Third Quarter	$0.44	$ 0.22
Fourth Quarter	$0.30	$ 0.09

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

As of March 25, 2013, there were 21,580,536 shares of our common stock outstanding and 64 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.”

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. In addition, the Senior Secured Notes restrict us from paying a dividend as long as the notes are outstanding. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth our securities authorized for issuance under our equity compensation plans as of December 31, 2012:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	-	-	-
Equity compensation plans not approved by security holders	5,229,330	$ 2.25	1,459,115
Total	5,229,330	$ 2.25	1,459,115

Stock Incentive Plans

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

On November 1, 2010, our board of directors approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the Stock Incentive Plan). The Stock Incentive Plan permits grants of awards to our employees, directors and advisors 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 Stock Incentive Plan is currently administered by our board of directors. The Stock Incentive Plan gives broad powers our board of directors to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive 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 our board of directors.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2012. You should read this table together with our financial statements and the related notes included in this prospectus.

	December 31, 2012
Cash and cash equivalents	$70,325
Subscriptions payable for senior secured convertible promissory notes	438,516
Notes payable, related parties	5,372,743
Stockholders' equity (deficit):	
Preferred stock, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding	-
Common stock, par value $0.001, 150,000,000 shares authorized and 21,007,536 issed and outstanding	21,008
Additional paid-in capital	64,357,193
Accumulated other comprehensive income	13,116
Accumulated deficit	(70,910,322)
Total Stockholders' deficit	(6,519,005)
Total Capitalization	$(707,746)

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of common stock and the net tangible book value per share of our common stock after this offering. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding. Dilution represents the difference between the amount per share paid by purchasers of our common stock in this offering and the net tangible book value per share of common stock immediately after the completion of this offering.

Dilution under assumption of sale of 100% of the shares offered in this offering.

Our net tangible book value (deficit) as of December 31, 2012 was ($7,746,030), or ($0.37) per share of common stock.

Without taking into account any other changes in net tangible book value after December 31, 2012, other than giving effect to (i) the sale of _____ shares of our common stock in this offering at an assumed public offering price of $_____ per share (the closing price of our common stock on _____, 2013); (ii) the conversion of our 18% Senior Secured Convertible Promissory Notes, in the principal amount of $_____, including accrued interest, at a conversion price of $0.20 per share; and (iii) less estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2012 would have been approximately $_____, or approximately $_____ per share. This represents an immediate increase in net tangible book value of $_____ per share to existing stockholders and an immediate dilution in net tangible book value of $_____ per share to new investors of common stock in this offering. If the offering price is higher or lower, the dilution to the new investors will be greater or less. The following table illustrates this per share dilution:

		Per Share
Assumed public offering price per share		$
Historical net tangible book value deficit per share as of December 31, 2012	$(0.37	)
Decrease in pro forma net tangible book value per share attributable to conversion of our 18% Senior Secured Convertible Promissory Notes as a result of this offering		
Increase in pro forma net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after this offering		$
Dilution per share to new investors		$

A $1.00 increase or decrease in the assumed public offering price of $_____ per share would increase or decrease, respectively, our pro forma as adjusted net tangible book value after this offering by approximately $_____, or approximately $_____ per share, and the dilution per share to new investors of common stock in this offering by approximately $_____ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after the conversion of our 18% Senior Secured Convertible Promissory Notes, in the principal amount of $_____, including accrued interest, at a conversion price of $0.20 per share, and deducting the estimated offering expenses payable by us.

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The following table sets forth, on a pro forma basis, as of December 31, 2012, the differences between the number of shares of common stock purchased from us, the total consideration paid, and the weighted average price per share paid by existing stockholders and new investors purchasing shares of our common stock in this offering, at an assumed public offering price of $_____ per share, the price set forth on the cover page of this prospectus, before deducting and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Weighted Average Price Per Share
Existing stockholders before this offering		%	$	%	$
Stockholders attributable to conversion of our 18% Senior Secured Convertible Promissory Notes as a result of this offering		%	$	%	$
New investors participating in this offering		%	$	%	$
Total		%	$	%	$

A $1.00 increase or decrease in the assumed public offering price of $_____ per share would increase or decrease, respectively, total consideration paid by new investors and total consideration paid by all stockholders by approximately $_____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after the conversion of our 18% Senior Secured Convertible Promissory Notes, in the principal amount of $_____, including accrued interest, at a conversion price of $0.20 per share, and after deducting the estimated placement agent fees and estimated offering expenses payable by us.

The foregoing illustration does not reflect potential dilution from the exercise of outstanding options or warrants to purchase shares of our common stock. If the holders of these derivative securities exercise them at a price per share that is less than the public offering price, our new investors will have further dilution.

Dilution under assumption of sale of 50% of the shares offered in this offering.

Our net tangible book value (deficit) as of December 31, 2012 was ($7,746,030), or ($0.37) per share of common stock.

Without taking into account any other changes in net tangible book value after December 31, 2012, other than giving effect to (i) the sale of _____ shares of our common stock in this offering at an assumed public offering price of $_____ per share (the closing price of our common stock on _____, 2013); and (ii) less estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2012 would have been approximately $_____, or approximately $_____ per share. This represents an immediate increase in net tangible book value of $_____ per share to existing stockholders and an immediate dilution in net tangible book value of $_____ per share to new investors of common stock in this offering. If the offering price is higher or lower, the dilution to the new investors will be greater or less. The following table illustrates this per share dilution:

	Per Share
Assumed public offering price per share	$
Historical net tangible book value deficit per share as of December 31, 2012	$ (0.37)
Increase in pro forma net tangible book value per share attributable to this offering	
Pro forma as adjusted net tangible book value per share after this offering	$
Dilution per share to new investors	$

A $1.00 increase or decrease in the assumed public offering price of $_____ per share would increase or decrease, respectively, our pro forma as adjusted net tangible book value after this offering by approximately $_____, or approximately $_____ per share, and the dilution per share to new investors of common stock in this offering by approximately $_____ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and deducting the estimated offering expenses payable by us.

The following table sets forth, on a pro forma basis, as of December 31, 2012, the differences between the number of shares of common stock purchased from us, the total consideration paid, and the weighted average price per share paid by existing stockholders and new investors purchasing shares of our common stock in this offering, at an assumed public offering price of $_____ per share, the price set forth on the cover page of this prospectus, before deducting and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Weighted Average Price Per Share
Existing stockholders before this offering		%	$	%	$
New investors participating in this offering		%	$	%	$
Total		%	$	%	$

A $1.00 increase or decrease in the assumed public offering price of $_____ per share would increase or decrease, respectively, total consideration paid by new investors and total consideration paid by all stockholders by approximately $_____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated placement agent fees and estimated offering expenses payable by us.

The foregoing illustration does not reflect potential dilution from the exercise of outstanding options or warrants to purchase shares of our common stock. If the holders of these derivative securities exercise them at a price per share that is less than the public offering price, our new investors will have further dilution.

Dilution under assumption of sale of 25% of the shares offered in this offering.

Our net tangible book value (deficit) as of December 31, 2012 was ($7,746,030), or ($0.37) per share of common stock.

Without taking into account any other changes in net tangible book value after December 31, 2012, other than giving effect to (i) the sale of _____ shares of our common stock in this offering at an assumed public offering price of $_____ per share (the closing price of our common stock on _____, 2013); and (ii) less estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2012 would have been approximately $_____, or approximately $_____ per share. This represents an immediate increase in net tangible book value of $_____ per share to existing stockholders and an immediate dilution in net tangible book value of $_____ per share to new investors of common stock in this offering. If the offering price is higher or lower, the dilution to the new investors will be greater or less. The following table illustrates this per share dilution:

	Per Share
Assumed public offering price per share	$
Historical net tangible book value deficit per share as of December 31, 2012	$ (0.37)
Increase in pro forma net tangible book value per share attributable to this offering	
Pro forma as adjusted net tangible book value per share after this offering	$
Dilution per share to new investors	$

A $1.00 increase or decrease in the assumed public offering price of $_____ per share would increase or decrease, respectively, our pro forma as adjusted net tangible book value after this offering by approximately $_____, or approximately $_____ per share, and the dilution per share to new investors of common stock in this offering by approximately $_____ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and deducting the estimated offering expenses payable by us.

The following table sets forth, on a pro forma basis, as of December 31, 2012, the differences between the number of shares of common stock purchased from us, the total consideration paid, and the weighted average price per share paid by existing stockholders and new investors purchasing shares of our common stock in this offering, at an assumed public offering price of $_____ per share, the price set forth on the cover page of this prospectus, before deducting and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Weighted Average Price Per Share
Existing stockholders before this offering		%	$	%	$
New investors participating in this offering		%	$	%	$
Total		%	$	%	$

A $1.00 increase or decrease in the assumed public offering price of $_____ per share would increase or decrease, respectively, total consideration paid by new investors and total consideration paid by all stockholders by approximately $_____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated placement agent fees and estimated offering expenses payable by us.

The foregoing illustration does not reflect potential dilution from the exercise of outstanding options or warrants to purchase shares of our common stock. If the holders of these derivative securities exercise them at a price per share that is less than the public offering price, our new investors will have further dilution.

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 a shockwave technology company using noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to solicit a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE

device for treating diabetic foot ulcers which is in a supplemental Phase III clinical study with possible FDA approval in 2015, subject to obtaining positive clinical study results.

In addition, we believe there are significant license/partnership opportunities for our shockwave technology in medical and non-medical uses, including energy, food and industrial markets, and we believe we have a broad intellectual property portfolio and broad know-how.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. We currently do not market any products in the United States. We generate our revenues from sales of our CE Mark devices and accessories in Europe, Canada and Asia/Pacific.

We believe we have demonstrated that our technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron, and orthoPACE devices in Europe. Our lead product candidate for the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

We are focused on developing our Pulsed Acoustic Cellular Expression (PACE) technology to activate healing in:

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

In addition to healthcare uses, our high-energy, acoustic pressure shockwaves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. We intend to seek to exploit such potential uses through licensing and/or partnership opportunities.

Recent Developments

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct an supplemental clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. We have identified and entered into contracts with clinical study sites and are in the process of negotiating contracts with additional sites for participation in the clinical trial. We expect that patient enrollment will begin in the second quarter of 2013.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the pivotal trial (discussed below). Similar to the pivotal trial, four (4) dermaPACE procedures will be administered during the first two weeks following subject enrollment. In the upcoming trial, however, up to four (4) additional dermaPACE procedures will be delivered bi-weekly, between weeks 4 and 10, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical study. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted pivotal study. Bayesian designs are supported by the FDA where there is strong prior evidence that can be incorporated into the clinical study design. By incorporating the prior positive information regarding complete wound closure after one treatment cycle into the design of the additional study, substantially fewer patients should be required than would otherwise be the case while still ensuring adequate statistical power. This approach will save significant time and preserve scientific rigor.

The supplemental clinical study will incorporate an independent group of medical professionals who will independently adjudicate wound closure of individual patients and correspond with the respective principal investigator if their decisions contradict the decisions made by the principal investigator to make a final determination on the state of closure of the wound.

Importantly, the study design allows for controlled interim monitoring of the data by an independent Data Monitoring Committee (DMC) to determine whether study success has been achieved. We anticipate that the first analysis of the success of the study will occur after 90 patients (approximately 45 per arm) have completed the 12-week primary efficacy evaluation period. If study data achieves pre-defined statistical and clinical success criteria associated with wound closure favoring dermaPACE, then the clinical trial can be stopped, and we will submit an amendment to the current PMA for approval. The controlled interim monitoring plan also includes a provision for DMC review of data prior to enrollment of the 90 subjects. This provision has been established in order to monitor the progress of the trial and ensure its alignment with our statistical plan, or to increase the sample size should additional subjects be needed to demonstrate study success, or stop the trial if study success is deemed unattainable. By monitoring the data in this way, we can take appropriate steps to allocate resources based on the direction the data is heading, prior to arriving at the 90 patient mark, which is the first point at which study success may be determined per our agreement with the FDA.

Previous clinical work supporting our current dermaPACE clinical study

The dermaPACE device completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA Application was filed with the FDA in June 2011. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the ITT population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) sham-control subjects.
- In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of sham-control subjects (p=0.047); in the efficacy evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of sham-control subjects (p=0.018).
- Subjects treated with dermaPACE achieved a significant increase in the rate of complete and/or ≥90% wound closure. We analyzed a clinically relevant ≥ 90% wound closure endpoint that demonstrated statistical significance (p=0.0161) in favor of dermaPACE subjects (51/107, 48%) compared to patients randomized to receive sham-control (31/99, 31%).
- Within 6 weeks following the initial dermaPACE procedure, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control ($p<0.05$).
- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20.0% in the sham-control group.
- Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

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

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's failure to meet the study's primary endpoint of 100% wound closure compared with sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency was for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we decided to conduct supplemental clinical work as discussed above.

Financial Overview

Since our inception in 2005, we have funded our operations from the sale of capital stock, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009, and product sales. At December 31, 2012, our balance of cash and cash equivalents totaled $70,325 and we had a net working capital deficit of $2,413,536. We will require additional capital from this offering to continue as a going concern through 2013. There can be no assurance that we will be successful in raising such capital. See “Liquidity and Capital Resources.”

We expect to continue to incur significant expenses as a result of the dermaPACE clinical study in the United States, as well as expenses associated with regulatory filings, which may include expenses related to responding to regulatory comments and/or directives following review of our filings/applications.

Since our inception, we have incurred losses from operations each year. As of December 31, 2012, we had an accumulated deficit of $70,910,322. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next several years as we continue to fund our clinical trials and the FDA approval process. We incurred net losses of $6,401,494 and $10,238,797 during the years ended December 31, 2012 and 2011, respectively. These operating losses create an uncertainty about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing will provide the necessary funding for us to continue as a going concern for the next year.

We cannot reasonably estimate the nature, timing and costs of the efforts necessary to complete the development and approval of, or the period in which material net cash flows are expected to be generated from, any of our products, due to the numerous risks and uncertainties associated with developing 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 effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior.

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

Critical Accounting Policies and Estimates

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

On an ongoing basis, we evaluate our estimates and judgments, including those related to the recording of the allowances for doubtful accounts, estimated reserves for inventory, estimated useful life of property and equipment, the determination of the valuation allowance for deferred taxes, the estimated fair value of stock-based compensation, the estimated fair value of intangible assets, the estimated fair value assigned to the capital stock units exchanged for promissory notes and the estimated fair value assigned to the common stock and warrants exchanged for the notes payable, related parties. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included with this prospectus, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, intangible assets, 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

We recognize sales of medical devices, including related applicators and applicator kits, when they are shipped to the customer. Shipments under agreements with distributors are invoiced at a fixed price, are not subject to return, and payment for these shipments is not contingent on sales by the distributor. We recognize revenue on shipments to distributors in the same manner as with other customers. We recognize fees from services performed 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 and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs.

Inventory Valuation

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

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

Intangible Assets

Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over the average life of 11.4 years. We regularly review intangible assets to determine if facts and circumstances indicate that the useful life is shorter than we originally estimated or that the carrying amount of the assets may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the intangible assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If recognition of an impairment charge is necessary, it is measured as the amount by which the carrying amount of the intangible asset exceeds the fair value of the intangible asset.

Stock-based Compensation

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

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

Income Taxes

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, Income Taxes (formerly SFAS No. 109, Accounting for Income Taxes). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets, including loss carryforwards, when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We account for uncertain tax positions in accordance with the related provisions 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 our 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.

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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, plastic/cosmetic and cardiac conditions.

Comprehensive Income (Loss)

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. 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.

Results of Operations for the Years ended December 31, 2012 and 2011

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2012 were $769,217, compared to $802,572 for the same period in 2011, a decrease of $33,355, or 4%. Revenues resulted primarily from sales in Europe of our dermaPACE and orthoPACE devices and related applicators. The decrease in revenues for 2012 is due to lower sales of orthoPACE devices in Europe for orthopedic, trauma and sports medicine indications due to the European economic downturn. This is partially offset by an increase in sales of applicators for 2012 as a result of more devices in use.

Cost of revenues for the year ended December 31, 2012 were $220,257, compared to $261,890 for the same period in 2011. Gross profit as a percentage of revenues was 71% for the year ended December 31, 2012, compared to 67% for the same period in 2011. The slight increase in gross profit as a percentage of revenues in 2012 was due to increased sales of higher margin applicators in 2012, as compared to 2011.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2012 were $1,762,194, compared to $2,731,059 for the same period in 2011, a decrease of $968,865, or 35%. 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 and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs. Research and development expenses in 2012 decreased due to lower expenses for clinical results analysis and clinical related expenses. Consulting expenses related to clinical results analysis were higher in 2011 as we prepared for the submission to the FDA in June 2011 of the dermaPACE PMA for treating diabetic foot ulcers.

We expect research and development expenses to increase in 2013 as a result of the expected start of the supplemental Phase III clinical trial of dermaPACE for treating diabetic foot ulcers in the United States, as well as continuing expenses associated with regulatory filings in addition to continuing technology development.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2012 were $4,521,957, as compared to $6,292,950 for the same period in 2011, a decrease of $1,770,993, or 28%. General and administrative expenses include non-cash stock-based compensation of $1,391,316 and $1,118,813 for the years ended December 31, 2012 and 2011, respectively. The increase in non-cash stock-based compensation of $272,503, or 24%, was primarily due to the stock options granted in November 2012 to the former President and Chief Executive Officer upon his resignation and the vesting of all his outstanding, unvested options at that time.

Excluding non-cash stock-based compensation, general and administrative expenses were $3,130,641 for the year ended December 31, 2012, as compared to $5,174,137 for the same period in 2011, a decrease of $2,043,496, or 39%. The decrease was primarily due to a reduction in headcount (10 employees in December 2012 as compared to 28 employees in December 2011), decreased investor relations expenses and decreased legal costs for patent defense activities.

We expect to continue to focus on keeping general and administrative expenses reduced to the 2012 expenditure rate in 2013.

Depreciation and Amortization

Depreciation for the year ended December 31, 2012 was $20,375, compared to $19,034 for the same period in 2011, an increase of $1,341, or 7%. The increase is due to full year depreciation in 2012 for assets purchased in 2011.

Amortization for the year ended December 31, 2012 was $306,757, compared to $306,756 for the same period in 2011.

Other Income (Expense)

Interest expense, net, for the year ended December 31, 2012 was $331,743, compared to $472,155 for the same period in 2011, a decrease of $140,412, or 30%. The decrease was due to no interest expense after April 4, 2011 on certain notes payable to related parties as a result of the note exchange for common stock and warrants on that date as discussed below.

In June 2009, we sold our veterinary division to Pulse Veterinary Technologies, LLC (Pulse Vet). Under terms of the asset purchase agreement, we continued to provide transitional production services at the direction of Pulse Vet for a fee until these services were transitioned to Pulse Vet. Pulse Vet took over production services effective November 1, 2011. The income for these transitional services was $0 and $375,000 for the years ended December 31, 2012 and 2011, respectively. The decrease was due to the discontinuation of the services effective November 1, 2011.

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

Provision for Income Taxes

At December 31, 2012, we had federal net operating loss carryforwards of $54,017,215 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a "more than 50% change in ownership" which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the year ended December 31, 2012 was $6,401,494, or $0.30 per basic and diluted share, compared to a net loss of $10,238,797, or $0.52 per basic and diluted share, for the same period in 2011. We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device FDA clinical trial for the treatment of diabetic foot ulcers.

Liquidity and Capital Resources

The continuation of our business is dependent upon raising additional capital. On March 8, 2013, we completed a private placement to accredited investors of an aggregate $2,000,000 of Senior Secured Notes. The Senior Secured Notes begin to mature in May 2013. The Senior Secured Notes will automatically convert to common stock if we raise $4,000,000 or more in gross proceeds through a qualified financing and/or license agreement as defined in the Senior Secured Note agreements. We plan to seek to obtain additional capital in 2013 through the issuance of common stock or other securities (such as in this offering) and we have engaged financial advisors to assist us. Based on our current financial condition, we may be unable to obtain such financing on commercially reasonable terms, if at all. If we do not raise at least $4,000,000, the Senior Secured Notes will not automatically convert to common stock and will become due and payable.

We expect to devote substantial resources to continue our supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers. Because of the significant time it will take for our product to complete the clinical trial process, and for us to obtain approval from regulatory authorities and successfully commercialize our product, we will require substantial additional capital resources. We incurred a net loss of $6,401,494 and $10,238,797 for the years ended December 31, 2012 and 2011, respectively. These operating losses create uncertainty about our ability to continue as a going concern. For the years ended December 31, 2012 and 2011, the net cash used by operating activities by us was $4,290,121 and $8,831,699, respectively. As of December 31, 2012, we had cash and cash equivalents of $70,325. We may raise additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, or an investment by a strategic partner in a specific clinical indication or market opportunity, or we may sell all or a portion of our assets. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

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

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

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

During the year ended December 31, 2010, we sold “Units” to select accredited investors which consisted of: (i) one share of common stock; (ii) a two-year common stock purchase warrant (Class D Warrant) to purchase one share of common stock, at an exercise price of $2.00; and (iii) an option (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. Between January 1 and January 31, 2011, Option holders exercised 1,950,167 Options for total gross proceeds of $3,900,334 to us. In connection with the exercise of Options in January 2011, we issued 1,950,167 shares of common stock and 1,950,167 Class D Warrants. The Option holders included our chairman of the board of directors who exercised 545,252 Options and the brother of a member of our board of directors who exercised 686,252 Options. The 132,500 Options that remained unexercised at January 31, 2011 expired by their terms.

For the year ended December 31, 2012, net cash used by operating activities was $4,290,121, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by financing activities for the year ended December 31, 2012 was $450,424, which primarily consisted of the proceeds received from subscriptions for the senior secured convertible promissory notes of $430,000. Cash and cash equivalents decreased by $3,839,058 for the year ended December 31, 2012.

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

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Contractual Obligations

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

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 $8,506, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the lease expired on July 31, 2010, and we extended the lease until October 31, 2015.

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

During the year ended December 31, 2012, we conducted a private offering to accredited investors of 18% Senior Secured Convertible Promissory Notes (as previously defined, the Senior Secured Notes). We received subscriptions for the Senior Secured Notes in the aggregate principal amount of $430,000 through December 31, 2012. Subsequent to December 31, 2012, we received subscriptions for an additional aggregate $1,570,000. We closed the offering and issued the aggregate $2,000,000 in Senior Secured Notes on March 8, 2013. The Senior Secured Notes have a six month term from the subscription date and the notes are convertible into common stock at any time at $0.20 per share. Upon the consummation of a qualified financing and/or technology license of $4,000,000 or more by us, as defined in the Senior Secured Note agreements, the principal and interest on the Senior Secured Notes will convert into common stock at a conversion price equal to the lower of (i) the price of our common stock issued in the qualified financing and/or technology license, reduced by a discount of 20%, and (ii) $0.20 per share. The Senior Secured Note holders will also receive, if any are issued, warrants or any other security issued in a qualified financing and/or technology license on similar terms to the qualified financing and/or technology license. The Senior Secured Notes are secured by our tangible and intangible assets. As of December 31, 2012, we had issued six Senior Secured Notes in the principal amount of $430,000 and had accrued interest expense of $8,516.

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, Inc., we issued two notes to HealthTronics, Inc. for $2,000,000 each. The notes bear interest at 6% annually. Quarterly interest through June 30, 2010 was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal is due August 1, 2015. Accrued interest on the notes not payable until August 2015 totaled $1,372,743 at December 31, 2012 and 2011.

Recently Issued Accounting Standards

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

Off-Balance Sheet Arrangements

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

Effects of Inflation

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

BUSINESS

Overview

We are a shockwave technology company using noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to solicit a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the demaPACE® device, used for treating diabetic foot ulcers, which is in a supplemental Phase III clinical study with possible FDA approval in 2015, subject to submission of satisfactory clinical study results.

In addition, we believe we have significant license/partnership opportunities for our shockwave technology in medical and non-medical uses, including energy, food and industrial markets, in addition to a broad intellectual property portfolio and broad know-how.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. We currently do not market any commercial products for sale in the United States. We generate our revenues from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada and Asia/Pacific.

We believe we have demonstrated that our technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron®, Evotron®, and orthoPACE® devices in Europe and Asia. Our lead product candidate for the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

We are focused on developing our Pulsed Acoustic Cellular Expression (PACE) technology to activate healing in:

- wound conditions, including diabetic foot ulcers, venous ulcers, pressure sores, burns and other skin eruption conditions;
- orthopedic applications, such as eliminating chronic pain in joints from trauma or arthritis, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;

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- 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.

In addition to healthcare uses, our high-energy, acoustic pressure shockwaves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

dermaPACE – Our lead product candidate

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a supplemental clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. We have already identified and entered into contracts with clinical study sites and are in the process of negotiating contracts with additional sites for participation in the clinical study. We expect that patient enrollment will begin in the second quarter of 2013.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the pivotal trial (discussed below). Similar to the pivotal trial, four (4) dermaPACE procedures will be administered during the first two weeks following subject enrollment. In the upcoming trial, however, up to four (4) additional dermaPACE procedures will be delivered bi-weekly, between weeks 4 and 10 following subject enrollment, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical study. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted pivotal study. Bayesian designs are supported by the FDA where there is strong prior evidence that can be incorporated into the clinical study design. By incorporating the prior positive information regarding complete wound closure after one treatment cycle into the design of the additional study, substantially fewer patients should be required than would otherwise be the case while still ensuring adequate statistical power. This approach will save significant time and preserve scientific rigor.

The supplemental clinical study will incorporate an independent group of medical professionals who will independently adjudicate wound closure of individual patients and correspond with the respective principal investigator if their decisions contradict the decisions made by the principal investigator to make a final determination on the state of closure of the wound.

Importantly, the study design allows for controlled interim monitoring of the data by an independent Data Monitoring Committee (DMC) to determine whether study success has been achieved. We anticipate that the first analysis of the success of the study will occur after 90 patients (approximately 45 per arm) have completed the 12-week primary efficacy evaluation period. If study data achieves pre-defined statistical and clinical success criteria associated with wound closure favoring dermaPACE, then the clinical trial can be stopped, and we will submit a PMA for approval. The controlled interim monitoring plan also includes a provision for DMC review of data prior to enrollment of the 90 subjects. This provision has been established in order to monitor the progress of the trial and ensure its alignment with our statistical plan, or to increase the sample size should additional subjects be needed to demonstrate study success, or stop the trial if study success is deemed unattainable. By monitoring the data in this way, we can take appropriate steps to allocate resources based on the direction the data is heading, prior to arriving at the 90 patient mark, which is the first point at which study success may be determined per our agreement with the FDA.

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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, Canada and Asia/Pacific, utilizing distributors in select countries.

Previous clinical work supporting our current dermaPACE clinical study

The dermaPACE device completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA Application was filed with the FDA in July 2011. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) sham-control subjects.
- In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of sham-control subjects (p=0.047); in the efficacy evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of sham-control subjects (p=0.018).
- Subjects treated with dermaPACE achieved a significant increase in the rate of complete and/or ≥90% wound closure. We analyzed a clinically relevant ≥ 90% wound closure endpoint that demonstrated statistical significance (p=0.0161) in favor of dermaPACE subjects (51/107, 48%) compared to patients randomized to receive sham-control (31/99, 31%).

- Within 6 weeks following the initial dermaPACE treatment, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control ($p<0.05$).
- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20.0% in the sham-control group.
- Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

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

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's failure to meet the study's primary endpoint of 100% wound closure compared with sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency was for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we decided to conduct supplemental clinical work, as discussed above.

Pulsed Acoustic Cellular Expression (PACE) Technology for regenerative medicine

Our PACE product candidates, including our lead product candidate, dermaPACE, deliver high-energy acoustic pressure waves in the shockwave spectrum to produce compressive and tensile stresses on cells and tissue structures. These mechanical stresses at the cellular level have been shown in pre-clinical work to promote angiogenic and positive inflammatory responses, and quickly initiate the healing cascade. This has been shown in pre-clinical work to result in microcirculatory improvement, including increased perfusion and blood vessel widening (arteriogenesis), the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE procedures trigger the initiation of an accelerated inflammatory response that speeds wounds into proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help reinitiate the body's own healing response. We believe that our PACE technology is well suited for various applications due to its activation of a broad spectrum of cellular events critical for the initiation and progression of healing.

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

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

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We believe our experience from our preclinical research and the clinical use of our predecessor legacy devices in Europe and Asia, as well as our OssaTron device in the United States, demonstrates the safety, clinical utility and efficacy of these products. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications.

Currently, there are limited biological or mechanical therapies available to activate the healing and regeneration of 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 pre-clinical and clinical studies suggest that our PACE technology will be effective in targeted applications. If successful, we anticipate that future clinical studies, including our dermaPACE clinical study in the United States for treating diabetic foot ulcers, should lead to regulatory approval of our regenerative product candidates in the United States, Europe and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and noninvasive treatment options in wound healing, orthopedic injuries, plastic/cosmetic uses and cardiac procedures, improving the quality of life for millions of patients suffering from injuries or deterioration of tissue, bones and vascular structures.

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Our primary interest is obtaining FDA approval for our lead product candidate, dermaPACE, for the wound care market, initially 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 (CDC) reported the total costs (direct and indirect) of diabetes in the United States is $174 billion annually, and people with diagnosed diabetes have medical expenditures that are over two times higher than medical expenditures for people without diabetes. Hospitalization costs alone are $16,000 to $20,000 for a patient with a diabetic foot ulcer, and direct and indirect costs of an amputation range from $20,000 to $60,000 per patient. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need globally, yet in short supply. According to the American Diabetes Association, by the year 2025 the prevalence of diabetes is expected to rise by 72% to 324 million people worldwide.

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

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

Developing Product Opportunities - Orthopedic

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

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

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

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

Non-Medical Uses For Our Shockwave Technology

We believe there are significant license/partnership opportunities for our shockwave technology in non-medical uses, including in the energy, water, food and industrial markets.

Due to their powerful pressure gradients and localized cavitational effects, we believe high-energy, acoustic pressure shockwaves can be used to clean, in an energy efficient manner, contaminated fluids from impurities, bacteria, viruses and other harmful micro-organisms, which provides opportunities for our technology in cleaning industrial and domestic/municipal waters. Based on the same principles of action of the shockwaves against bacteria, viruses and harmful micro-organisms, we believe our technology can be applied for cleaning or sterilization of various foods as milk, natural juices and meats.

In the energy sector, we believe shockwaves can be used to improve oil recovery (IOR), as a supplement to or in conjunction with existing fracking technology, which utilizes high pressurized water/gases to crack the rocks that trap oil in the underground reservoir, through the use of our high-energy, acoustic pressure shockwaves to improve the efficiency and reduce the environmental impact of the fracking process. Furthermore, we believe our technology can be used for enhanced oil recovery (EOR) based on the changes in fluid flow characteristics resulting from shockwave stimulation, as a tertiary method of oil recovery from older oil fields.

Additionally, we believe high-energy, acoustic pressure shockwaves can disrupt biofilms and thus can be used to unclog pipes in the energy industry (shore or off-shore installations), food industry and water management industry, which will reduce or eliminate down times with significant financial benefits for maintenance of existing infrastructure.

Market Trends

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

According to AdvaMed and Centers for Medicare & Medicaid Services data and our internal projections, 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 and their desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

With the success of negative pressure wound therapy devices in the wound care market over the last decade and the recognition of the global epidemic associated with certain types of wounds, as well as deteriorating musculoskeletal conditions attributed to 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 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 market participants are interested in biological response activating devices that are applied noninvasively and seek to activate the body’s own capabilities for regeneration of tissue at injury sites in a cost-effective manner.

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Strategy

Our primary objective is to be a leader in the development and commercialization of our shockwave technology, which utilizes noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to solicit a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE device for treating diabetic foot ulcers, which is in a final Phase III clinical study with possible FDA approval in 2015 subject to submission of satisfactory clinical study results. In addition, we believe we have significant license/partnership opportunities for our shockwave technology in medical and non-medical uses, including energy, food and industrial markets, a broad intellectual property portfolio and know-how.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions.

Our immediate goal for our regenerative medicine technology involves leveraging the knowledge we gained from our existing human heel and elbow indications to enter the advanced wound care market with innovative treatments.

The key elements of our strategy include the following:

- Obtain FDA approval for our dermaPACE device to treat diabetic foot ulcers.

We are focusing initially on obtaining FDA approval for our lead product candidate, dermaPACE, for the wound care market, initially in the United States for diabetic foot ulcers which we believe represents a large, unmet need. The FDA has granted approval of our IDE Supplement to conduct a supplemental clinical trial of the dermaPACE device in the treatment of diabetic foot ulcers. We have already identified and entered into contracts with clinical study sites and are in the process of negotiating contracts with additional sites for participation in the clinical study. We expect patient enrollment to begin in the second quarter of 2013.

- Develop and commercialize our noninvasive biological response activating devices in the regenerative medicine area 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, plastic/cosmetic and cardiac indications, possibly through potential license and/or partnership arrangements.

- License and seek partnership opportunities for our non-medical shockwave technology platform, know-how and extensive patent portfolio.

We intend to use our shockwave technology and know-how for non-medical uses, including energy, food, water and industrial markets, through license/partnership opportunities.

- Support the global distribution of our products.

Our portfolio of products, the dermaPACE and orthoPACE, are CE Marked and sold through select distributors in certain countries in Europe, Canada and Asia/Pacific. Our revenues are from sales of the devices and related applicators in these markets. We currently do not have any commercial products available for sale in the United States. We intend to continue to add additional distribution partners in Europe and Asia/Pacific.

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 development, and clinical indications.

We pay consulting fees to certain members of our scientific advisory board for the services they provide to us, in addition to reimbursing them for incurred expenses. The amounts vary depending on the nature of the services. We paid our advisors aggregate consulting fees through the issuance of stock options in 2012 and recorded stock based compensation expense of $27,750 for the year ended December 31, 2012. We paid our advisors aggregate consulting fees of $37,500 for the year ended December 31, 2011.

Sales, Marketing and Distribution

We do not have any commercial products available for sale in the United States. We currently do not have the sales or marketing resources required to commercialize our products in the United States. Following FDA approval, we intend to seek a development and/or commercialization partnership, or to commercialize a product ourselves. Outside the United States, we retain distributors to represent our products in selective international markets. These distributors have been selected based on their existing business relationships and the ability of their sales force and distribution capabilities to effectively penetrate the market with our PACE product line. We rely on these distributors to manage physical distribution, customer service and billing services for our international customers.

Manufacturing

We have developed a network of suppliers, manufacturers and contract service providers to provide sufficient quantities of our products.

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

Our facility in Alpharetta, Georgia consists of 5,168 square feet and provides office, research and development, quality control, production and warehouse space. It is a FDA registered facility and is ISO 13485 certified (for meeting the requirements for a comprehensive management system for the design and manufacture of medical

devices).

Intellectual Property

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

Patents

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

We derive our patent rights, including as to both issued patents and “patent pending” applications, from three sources: (1) assignee of patent rights in technology we developed; (2) assignee of patent rights purchased from HealthTronics, Inc. (“HealthTronics”); and (3) as licensee of certain patent rights assigned to HealthTronics. In August 2005, we purchased a 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 primarily for urological uses. We believe that our owned and licensed patent rights provide a competitive advantage with respect to others that might seek to utilize certain of our apparatuses and methods incorporating extracorporeal 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 seventeen issued United States patents and seven issued foreign patents which on average have remaining useful lives of ten years or longer. 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 seven United States non-provisional patent applications and two 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 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 (Ortho Field). HealthTronics receives field-exclusive and sublicensable rights under the purchased portfolio as to (1) certain HealthTronics lithotripsy devices in all fields other than the Ortho Field, and (2) all products in the treatment of renal, ureteral, gall stones and other urological conditions (Litho Field). HealthTronics also receives non-exclusive and non-sublicensable rights in the purchased portfolio as to any products in all fields other than the Ortho Field and Litho Field.

Pursuant to mutual amendment and other assignment-back rights under the patent license agreement with HealthTronics, we are also a licensee of certain patents and patent applications that have been assigned to HealthTronics. We received a perpetual, non-exclusive and royalty-free license to nine (9) issued foreign patents. Our non-exclusive license is subject to HealthTronics' sole discretion to further maintain any of the patents and pending applications assigned back to HealthTronics.

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

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

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

If we become involved in future litigation or any other adverse intellectual property proceeding, for example, as a result of an alleged infringement, or a third party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, including treble damages, invalidation of our intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business, financial condition and results of operation. In addition, any claims relating to the infringement of third party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation or lengthy governmental proceedings and could divert management's attention and resources and require us to enter into royalty or license agreements which are not advantageous, if available at all.

Trademarks

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

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

We also maintain trademark registrations for: OssaTron® (United States and Germany), evoPACE® (Australia, European Community and Switzerland), Evotron® (United States, Germany and Switzerland), Evotrode® (Germany and Switzerland), HMT® (Switzerland), Orthotripsy® (United States), Reflectron® (Germany and Switzerland), Reflectrode® (Germany and Switzerland), CSWT® (Switzerland), OSWT® (Switzerland) and TSWT® (Switzerland).

We have filed pending trademark applications for: dermaPACE™ (Canada), angioPACE™ (United States), PACE™ (Canada) and Profile™ (United States, European Community and Switzerland).

Potential Intellectual Property Issues

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

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

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

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

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

Competition

We believe the advanced wound care market can benefit from our technology which up-regulates the biological factors that promote wound healing. Current technologies developed by Kinetic Concepts, Inc. ("KCI"), Advanced BioHealing, Inc. (acquired by Shire plc in 2011), Organogenesis, Inc., Smith & Nephew plc, Integra LifeSciences Holdings Corporation and Systagenix Wound Management (US), Inc. manage wounds, but, in our opinion, do not provide the value proposition to the patients and care givers like our PACE technology has the potential to do. The leading medical device serving this market is the Vacuum Assisted Closure ("V.A.C.") System marketed by KCI. The V.A.C. is a negative pressure wound therapy device that applies suction to debride and better manage wounds.

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

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

Regulatory Matters

FDA Regulation

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

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

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

FDA Approval or Clearance of Medical Devices

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

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: special controls, pre-market notification (510(k)), specific controls such as performance standards, patient registries, and 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 on the basis that dermaPACE is a Class III device requiring a PMA approval. To date, we have corresponded with the FDA pertaining to possible reclassification of PACE technology for certain indications within the Class II designation. The FDA continues to maintain that PACE should remain a Class III technology. Reclassification of the technology is possible but the path through the FDA for such reclassification will be lengthy and involved. In the meantime, we may leverage existing PMA approval for our OssaTron device in order to obtain the same indication (treatment of plantar fasciitis) for our orthoPACE device as a line extension for the technology. This route may not require clinical trials and will be time effective.

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

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A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with Quality System Regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances where the FDA has not. If the FDA finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

During the review of either a PMA application or 510(k) submission , the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. We cannot be sure that our product candidates will be approved or cleared in a timely fashion or at all. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

We do not anticipate device regulatory pathways via the 510(k) route with our current technology. The FDA continues to stress that our products remain Class III, thus requiring the PMA approval pathway. In the past, the 510(k) pathway for product marketing required only the proof of significant equivalence in technology for a given indication with a previously cleared device. Currently, there has been a trend of the FDA requiring additional clinical work to prove efficacy in addition to technological equivalence. Thus, no matter which regulatory pathway we may take in the future towards marketing products in the United States, we will be required to provide clinical proof of device effectiveness.

Within the past year, the FDA has released new guidelines for the FDA's reviewers to use during a product's submission review process. This guidance provides the FDA reviewers with a uniform method of evaluating the benefits verses the risks of a device when used for a proposed specific indication. Such a benefit/risk evaluation is very useful when applied to a novel device or to a novel indication and provides the FDA with a consistent tool to document their decision process. While intended as a guide for internal FDA use, the public availability of this guidance allows medical device manufacturers to use the review matrix to develop sound scientific and clinical backup to support proposed clinical claims and to help guide the FDA, through the decision process, to look at the relevant data. We intend to use this benefit/risk tool in our FDA submissions.

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

Clinical Trials of Medical Devices

One or more clinical trials are almost always required to support a PMA application and more recently are becoming necessary to support a 510(k) submission. Clinical studies of unapproved or 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 (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 are our suppliers, contract manufacturers, and contract testing laboratories.

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

Manufacturing cGMP Requirements

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

International Regulation

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

The primary regulatory environment in Europe is the European Union, which consists of 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 body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have an ISO 13485:2003 certification, as well as meet additional requirements of Canadian laws. We currently maintain this certification. We maintain a device license for dermaPACE with Health Canada for the indication of "devices for application of shockwaves (pulsed acoustic waves) on acute and chronic defects of the skin and subcutaneous soft tissue".

The primary regulatory bodies and paths in Asia and Australia are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through

a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice (GMP), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with GMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

United States Anti-Kickback and False Claims Laws

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

Third Party Reimbursement

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

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

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

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

The initial phase of establishing a professional billing code for a medical service typically includes applying for a CPT Category III code. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as American Medical Association (AMA) CPT Editorial Panel review. A new CPT Category III code will be assigned if the AMA CPT Editorial Panel committee deems it meets the applicable criteria and is appropriate. In 2011, we received two CPT Category III codes for extracorporeal shock wave therapy (ESWT) in wound healing.

The secondary phase in the CPT billing code process includes the establishment of a permanent CPT Category I code in which relative value is analyzed and established by the AMA. The approval of this code, is based on, among other criteria, widespread usage and established clinical efficacy of the medical service.

There are also billing codes that facilities, rather than health care professionals, utilize for the reimbursement of operating costs for a particular medical service. For the hospital outpatient setting, the Centers for Medicare & Medicaid Services automatically classified the new ESWT wound healing CPT Category III codes into interim APC groups. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment.