BSQUARE CORP /WA
Form 4
August 15, 2007

FORM 4

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

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

OMB APPROVAL

OMB Number:	3235-0287
Expires:	January 31, 2005
Estimated average burden hours per response...	0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).

(Print or Type Responses)

1. Name and Address of Reporting Person *
BIBEAULT DONALD B

(Last) (First) (Middle)

110 - 110TH AVENUE, NE, SUITE 200

(Street)

BELLEVUE, WA 98004

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
BSQUARE CORP /WA [BSQR]

3. Date of Earliest Transaction (Month/Day/Year)
08/14/2007

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

__X__ Director _____ 10% Owner
_____ Officer (give title below) _____ Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			
Common Stock	08/14/2007		A		3,000	A	$ 0	163,633	D	

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)		5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)		6. Date Exercisable and Expiration Date (Month/Day/Year)		7. Title and Amount of Underlying Securities (Instr. 3 and 4)		8. Price of Derivative Security (Instr. 5)	9. Nu Deriv Secur Bene Owne Follo Repo Trans (Instr
				Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares		

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
BIBEAULT DONALD B 110 - 110TH AVENUE, NE SUITE 200 BELLEVUE, WA 98004	X			

Signatures

/s/ Scott C. Mahan for Donald B. Bibeault by Power of Attorney	08/15/2007
**Signature of Reporting Person	Date

Explanation of Responses:

* If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
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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).

Explanation of Responses:

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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Explanation of Responses: 18

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.

Explanation of Responses:

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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Explanation of Responses: 25

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).

Explanation of Responses:

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.

Explanation of Responses: 33

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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Explanation of Responses: 35

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.

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

Explanation of Responses: 41

Environmental and Occupational Safety and Health Regulations

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

Milestone and Royalty Payments

Under an agreement with Sci-Do AG, an Austrian company from which we purchased certain patents, we are required to make various milestone and royalty payments based on the occurrence of certain events. Pursuant to the terms of the agreement, we are required to make a royalty payment of $100,000 upon FDA approval of our product for wound care. In addition, we are required to make royalty payments, based on a percentage of operating profit, for sales of FDA-approved wound care products in excess of $500,000 of earnings before interest and taxes. There were no payments under the agreement for the years ended December 31, 2012 and 2011.

Research and Development

During the years ended December 31, 2012 and 2011, we spent $1,762,194 and $2,731,059 on research and development activities, respectively, which consists primarily of clinical trial expenses.

Employees

As of March 25, 2013, we had a total of eleven full time employees in the United States. Of these, six were engaged in research and development which includes clinical, regulatory and quality. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

Properties

Our operations, production and research and development office is in a leased facility in Alpharetta, Georgia, consisting of 5,168 square feet of space under a lease which expires on October 31, 2015. Under the terms of the lease, we pay monthly rent of $8,506, subject to adjustment on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount.

Legal proceedings

Other than the legal proceeding described below and those relating to our intellectual property, there are no material pending legal proceedings to which we are a party or of which any of our properties are subject; nor are there material proceedings known to us to be contemplated by any governmental authority. We have one pending legal proceeding

relating to our patents. For information regarding this legal proceeding, please see “Business - Intellectual Property - Patents” above.

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

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

MANAGEMENT, EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE

Management and Board of Directors

Below are the names and certain information regarding our executive officers and directors:

Name	Age	Position Held
Joseph Chiarelli	66	Chief Executive Officer and Director
Barry J. Jenkins	50	Chief Financial Officer and COO
Kevin A. Richardson, II	44	Director
John F. Nemelka	47	Director

Joseph Chiarelli has served as our Chief Executive Officer and a director since February of 2013. Mr. Chiarelli brings to our board of directors a broad array of financial knowledge for healthcare and other industries. Prior to joining us, he was Senior Managing Director for Auriga Capital Management where he was responsible for financial advisory, business development and a healthcare hedge fund from 2011 to February 2013. Previously, from 2008 to 2011, he was Managing Director of Chiarelli & Company, a firm providing strategic and financial advice to emerging and small companies. Mr. Chiarelli was Senior Managing Director for Wall Street Access where he managed a healthcare joint venture and independent healthcare research from 2007 to 2008. Previously, from 2005 to 2007, he was Chairman of the board of directors of Clarent Hospital Corporation, a hospital management firm. Mr. Chiarelli was a Senior Equity Investment Analyst at Oppenheimer & Co. Inc. where he managed the healthcare research team from 2003 to 2005. Previously, from 2002 to 2003, he was Managing Director of Blaylock & Partners, LP. Mr. Chiarelli was with JPMorgan Chase & Co. (JPM) from 1981 to 2001 where he developed much of his healthcare industry knowledge while he was responsible for three healthcare sectors as the Senior Investment Research Analyst. Prior to his assignment to healthcare, he served in a number of senior positions across JPM, including being Chief Financial Officer of two large independent subsidiaries, J.P. Morgan Delaware and Morgan Securities Services Corporation. Mr. Chiarelli is a Colonel in the USAFR and a member of the board of directors of a private healthcare device maker. He graduated from Manhattan College with a BBA in Accounting, earned an MBA in Management/Finance from the University of Hawaii, graduated from the Cornell University Executive Development Program, and is a graduate of Air War College. He is a certified public accountant and holds FINRA licenses 7, 24, 63, 86, and 87.

Kevin A. Richardson, II has served as chairman of the board of directors since October of 2009 and joined SANUWAVE, Inc. as chairman of the board of directors in August of 2005. In November 2012, upon the resignation of our former President and Chief Executive Officer, Christopher M. Cashman, Mr. Richardson assumed the role of Active Chief Executive Officer, in addition to remaining Chairman of the Board, through the hiring of Mr. Chiarelli in February 2013. Mr. Richardson brings to our board of directors a broad array of financial knowledge for healthcare and other industries. Since 2004, Mr. Richardson has served as managing partner of Prides Capital LLC, an investment management firm. Mr. Richardson is also a member of the board of directors of As Seen On TV, Inc., a publicly traded company, and Pegasus Solutions, Inc., a travel technology company.

Barry J. Jenkins has served as our Chief Financial Officer since September of 2009 and joined SANUWAVE, Inc. as Chief Financial Officer in April of 2006. Since November 2012, Mr. Jenkins has also served as our Chief Operating Officer. Prior to joining SANUWAVE, Inc., he served as Chief Financial Officer for the Benefit Services Division of Automatic Data Processing, Inc. from March of 2005 to April of 2006. Previously, he was the Chief Financial Officer of Snowden Pencer, Inc. from January of 2002 to November of 2004. Mr. Jenkins is a certified public accountant with 29 years of financial management experience and a cum laude graduate of Virginia Tech.

John F. Nemelka has served as a member of our board of directors since October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Nemelka brings to our board of directors a diverse background with both financial and operations experience. Since 2001, Mr. Nemelka has served as a managing principal of NightWatch Capital Advisors, LLC, an investment management firm. Mr. Nemelka is also a member of the board of directors of LiqTech International, Inc., a publicly traded clean technology company.

Director Independence

As a result of the resignation of four board members during 2012 for personal reasons and not attributable to any disagreement with us on any matter, our current board of directors consists of three members, none of whom has been determined by the board to be “independent” as defined under the rules of the NASDAQ stock market. We expect to add independent directors to the board of directors in 2013.

Board’s Leadership Structure

Our board of directors elects our chief executive officer and its chairman, and each of these positions may be held by the same person or may be held by two persons. Our board of directors has determined that it is currently in our best interest of to separate the roles of chairman of the board and chief executive officer. The chairman’s primary responsibilities are to manage the board and serve as the primary liaison between the board of directors and the chief executive officer, while the primary responsibility of the chief executive officer is to manage our day-to-day affairs, taking into account the policies and directions of the board of directors. Such an arrangement promotes more open and robust communication among the board, and provides an efficient decision making process with proper independent oversight. Following the resignation of Christopher M. Cashman as President and Chief Executive Officer, and a director, effective November 7, 2012, the board of directors elected Kevin A. Richardson, the chairman of the board, to also assume the function of Active Chief Executive Officer until Joseph Chiarelli joined us in February 2013 as Chief Executive Officer and a director. Mr. Richardson remained chairman of the board.

We believe, however, that there is no single leadership structure that is the best and most effective in all circumstances and at all times. Accordingly, the board of directors retains the authority to combine these roles in the future if doing so would be in the best interests of us and our shareholders.

Our board of directors is authorized to have an audit committee, a compensation committee and a nominating and corporate governance committee, to assist our board of directors in discharging its responsibilities. As a result of the resignation of four board members during 2012, the current board of directors consists of three members, none of whom have been determined by the board to be "independent" as defined under the rules of the NASDAQ stock market. We expect to add independent directors to the board of directors in 2013.

Board's Role in Risk Oversight

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

Code of Conduct and Ethics

Our policy is to conduct our affairs in accordance with all applicable laws, rules and regulations of the jurisdictions in which we do business. We have adopted a code of business conduct and ethics with policies and procedures that apply to all associates (all employees are encompassed by this term, including associates who are officers) and directors, including the chief executive officer, chief financial officer, controller, and persons performing similar functions.

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

No Family Relationships Among Directors and Officers

There are no family relationships between any director or executive officer of our and any other director or executive officer of ours.

Summary Compensation Table for Fiscal Years 2012 and 2011

The following table provides certain information concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2012 and 2011.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(5)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II	2012	- (1)	-	-	-	-	-	-	-
Chairman of the Board and Active	2011	-	-	-	-	-	-	-	-
Chief Executive Officer (principal executive officer)									
Barry J. Jenkins	2012	$ 245,417	-	-	-	-	-	$ 18,316	$ 263,733
Chief Financial Officer and COO (principal financial officer)	2011	$ 240,547	$ 182,532 (2)	-	-	-	-	$ 23,197	$ 446,276
Christopher M. Cashman	2012	$ 328,237 (3)	-	-	-	-	-	$ 784,315 (6)	$ 1,112,552
Former Chief Executive Officer and President	2011	$ 385,000	$ 415,000 (2)	-	$ 1,495,000 (4)	-	-	$ 26,220	$ 2,321,220

(1) Mr. Richardson has been Chairman of the Board since our inception and does not receive a salary. In addition, effective November 7, 2012, he assumed the additional position of Active Chief Executive Officer until Joseph Chiarelli joined us as Chief Executive Officer in February 2013. He did not receive compensation for being Active Chief Executive Officer in 2012.
(2) This includes two years of bonuses earned (2009 and 2010) which were paid in 2011.
(3) Salary through resignation date of November 7, 2012.
(4) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10. Mr. Cashman was granted options to purchase 1,300,000 shares of common stock at $1.98 per share on October 24, 2011. See note 15 to the financial statements.
(5) Includes health, dental, life and disability insurance premiums and employer 401(k) matching contributions.
(6) This dollar amount includes the full fair value of the severance payments for Mr. Cashman and the full fair value at date of grant of the stock options issued to Mr. Cashman in his severance agreement. Severance payments totaling $542,269 at December 31, 2012 were accrued for accounting purposes and are included in the total, however they will

be paid in future periods.

Employment Agreements

Joseph Chiarelli

General Terms. Pursuant to his employment agreement, Mr. Chiarelli joined us as Chief Executive Officer and a director on February 25, 2013 with a two year term thereafter extendable for one year periods. Mr. Chiarelli is entitled to an annual base salary of $200,000 for the first year and $225,000 thereafter, with a performance and compensation review not less often than annually, at which time compensation may be adjusted as determined by the board of directors.

In the event of the satisfaction of the following milestones, we shall award and pay to Mr. Chiarelli a cash bonus as follows: (i) $35,000 for us completing a financing resulting in gross proceeds to us of no less than $5.0 million at a price per share of not less than $0.35; (ii) $25,000 when the final patient is enrolled in our dermaPACE Phase III clinical trial; (iii) $25,000 upon receipt by us of FDA approval for the use of dermaPACE; and (iv) $25,000 upon the execution by us of a license or distribution agreement from which we are entitled to receive gross proceeds of no less than $1.0 million and we have received payments of at least $250,000. In addition, with respect to each full fiscal year, Mr. Chiarelli is eligible to earn an annual bonus award as determined by the board of directors based on the achievement of certain performance goals established by the board of directors. Mr. Chiarelli is also entitled to participate in our employee benefit plans (other than annual bonus and incentive plans). The employment agreement contains an agreement not to compete, which covers the term of employment and two years thereafter, and a confidentiality provision, which is indefinite.

Equity Arrangements. Upon the execution of his employment agreement, Mr. Chiarelli was granted options to purchase 2,250,000 shares of common stock, at an exercise price of $0.35 per share. The options vest and become exercisable in five installments as follows: (i) 375,000 vested at grant; (ii) 375,000 vest upon us completing a financing resulting in gross proceeds to us of no less than $5.0 million at a price per share of not less than $0.35; (iii) 375,000 upon the execution by us of a license or distribution agreement from which we are entitled to receive gross proceeds of no less than $1.0 million and our receiving payments of at least $250,000; (iv) 375,000 vest upon receipt by us of FDA approval for the use of dermaPACE; and (v) 750,000 vest in the event we achieve the milestones (i), (ii), (iii) and (iv) above during the initial two year term and the term is not extended by us.

Termination. Mr. Chiarelli's employment may be terminated by either party at any time and for any reason; provided that Mr. Chiarelli will be required to give us at least 30 days advance written notice of any resignation. If Mr. Chiarelli is terminated by us for cause or resigns without good reason, he will be entitled to receive his (1) base salary through the termination date, (2) reimbursement for certain unreimbursed business expenses, and (3) such employee benefits to which he may be entitled under our employee benefit plans. If Mr. Chiarelli is terminated by us without cause or resigns for good reason, he will be entitled to receive all of the above plus (1) subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, continued payment of the base salary through February 25, 2015, (2) continued payment of the bonus events discussed above as the milestones are achieved by us, and (3) all his options will vest.

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

Barry J. Jenkins

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

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Explanation of Responses: 50

Equity Arrangements. Upon the execution of his employment agreement, Mr. Jenkins was granted options to purchase 104,677 shares of common stock, at an exercise price of $2.92 per share. The options vested and became exercisable in four equal installments on April 10, 2007, 2008, 2009 and 2010. Upon the execution of his employment agreement and his commencement of employment, Mr. Jenkins purchased 35,089 shares of common stock, at a purchase price of $2.92 per share. In addition, upon the execution of his employment agreement, Mr. Jenkins was granted three supplemental options to purchase common stock. The terms of the supplemental options were amended on September 15, 2009. The first and second supplemental options each provided him with the right to purchase 34,778 shares of common stock and the third supplemental option provided him with the right to purchase 52,166 shares of common stock. The initial exercise price of the supplemental options is $2.92 per share. The supplemental options were fully vested on April 10, 2012.

Termination. Mr. Jenkins' employment may be terminated by either party at any time and for any reason; provided that Mr. Jenkins will be required to give us at least 30 days advance written notice of any resignation. If Mr. Jenkins is terminated by us for cause or resigns without good reason, he will be entitled to receive his (1) base salary through the termination date, (2) any annual bonus earned, but unpaid as of the date of termination for the immediately preceding fiscal year, (3) reimbursement for certain unreimbursed business expenses, and (4) such employee benefits to which he may be entitled under the employee benefit plans of ours. If Mr. Jenkins is terminated by us without cause or resigns for good reason, he will be entitled to receive all of the above plus (1) subject to his compliance with certain other provisions of the employment agreement related to non-competition and confidentiality and the execution of an effective release of claims, continued payment of the base salary until six months following the date of termination, and (2) continued coverage of him and his beneficiaries under our health insurance programs for a period of up to six months.

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

Severance Agreements

Christopher M. Cashman

Severance Agreement Terms. On November 6, 2012, we entered into a Severance and Advisory Agreement (Severance Agreement) with Christopher M. Cashman, then a director of ours, and our President and Chief Executive Officer. Entry into the Severance Agreement was made in connection with Mr. Cashman's resignation as President and Chief Executive Officer, and a director of our, effective November 7, 2012.

Pursuant to the Severance Agreement, Mr. Cashman will receive, as severance:

(a) six (6) months of his base salary, payable in accordance with our standard payroll practices;

(b) Company-paid COBRA coverage under our health care plan for himself and his family through November 2013;

(c) bonus payments of $100,000 upon each of the following four bonus payment events (Bonus Payment Events): (i) the first (1st) enrollee in our clinical trial plan, (ii) the twentieth (20th) enrollee, (iii) the fiftieth (50th) enrollee, and (iv) receipt of an FDA approval letter of the dermaPACE device allowance for commercial use; provided, that if the FDA approval letter at subpart (iv) is received prior to the achievement of the enrollment thresholds at subparts (i), (ii), and/or (iii), the bonuses for achievement of subparts (i), (ii), and/or (iii) will be accelerated and become due and payable immediately with the bonus for subpart (iv);

(d) a grant of 1,000,000 options to acquire shares of our common stock. The exercise price for such options is $0.21 which was the closing price of our common stock on the grant date. The term of the options is ten years. The first 600,000 options vested upon the execution of the Severance Agreement. The remaining 400,000 options will vest and become exercisable in increments of 100,000 upon each of the Bonus Payment Events at subparts (i)-(iv) above; provided, that if the FDA approval letter at subpart (iv) is received prior to the achievement of the enrollment thresholds at subparts (i), (ii), and/or (iii), all options granted under this section but not previously vested shall become vested and immediately exercisable upon receipt of such letter; and

(e) a grant of 50,000 options to acquire shares of our common stock under the Stock Incentive Plan as consideration for the provision of advisory services. The exercise price for such options is $0.21which was the closing price of our common stock on the grant date. The term of the options is ten years. The options will vest and be exercisable based on the following schedule: (i) 25% of the options vested upon the execution of the Severance Agreement, but will be forfeited if Mr. Cashman fails to provide advisory services as called for in the Severance Agreement; and (ii) unless the advisory services have been terminated, an additional 25% of the options shall vest on each date three (3), six (6), and nine (9) months after the effective date of the Severance Agreement.

Any of the Bonus Payment Events which have not occurred as of December 31, 2016 will be considered to have occurred as of December 31, 2016, and the remaining previously unpaid bonus payments per Bonus Payment Event will be due and payable immediately and all options granted under this section but not previously vested will become vested and immediately exercisable on such date.

Our board of directors authorized us to vest all previously granted but non vested stock options for Mr. Cashman, which will remain exercisable for the full term of their grant, notwithstanding any contrary provision in the applicable award agreements.

In connection with the entry by us and Mr. Cashman into the Severance Agreement, and the resignation of Mr. Cashman from his position as President and Chief Executive Officer, and as a director, the Employment Agreement, dated December 19, 2005, as amended (Employment Agreement), by and between us and Christopher M. Cashman was terminated, as of November 6, 2012. By the terms of the Severance Agreement, the Employment Agreement is of no further force or effect, as of the date of entry into the Severance Agreement, and, specifically, the terms of severance contained in the Severance Agreement supersede any such terms contained in the Employment Agreement.

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. (2006 Plan). On November 1, 2010, we approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (previously defined as the Stock Incentive Plan). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of ours 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 to the 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 by the board of directors. The Stock Incentive Plan initially had 5,000,000 shares of common stock reserved for grant, which amount has subsequently been increased to 8,500,000 in February 2013.

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

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

On December 31, 2012, there were 1,459,115 shares of common stock available for grant under the Stock Incentive Plan. For the years ended December 31, 2012 and 2011, there were 1,050,000 and 1,300,000 options granted to our executive officers under the Stock Incentive Plan, respectively.

Outstanding Equity Awards at 2012 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2012.

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II	5,000	-	-	$ 2.92	09/15/2019	-	-	-	-
(Chairman of the Board and Active CEO)	2,500	2,500 (2)	-	$ 4.05	01/29/2020	-	-	-	-
	5,000	-	-	$ 2.00	11/01/2020	-	-	-	-
Barry J. Jenkins	477,759	-	-	$ 2.92	10/24/2016	-	-	-	-
(Chief Financial Officer and COO)	10,000 (2)	10,000 (2)	-	$ 4.05	01/29/2020	-	-	-	-
	175,000	-	-	$ 2.00	11/01/2020	-	-	-	-
Christopher M. Cashman	1,210,686	-	-	$ 2.92	12/19/2015	-	-	-	-
(former President and CEO)(1)	350,000	-	-	$ 2.00	11/01/2020	-	-	-	-
	1,300,000	-	-	$ 1.98	10/24/2021	-	-	-	-
	600,000 (3)	400,000 (3)	-	$ 0.21	11/06/2022	-	-	-	-
	12,500 (4)	37,500 (4)	-	$ 0.21	11/06/2022	-	-	-	-

(1) Mr. Cashman resigned as President and CEO effective November 7, 2012.
(2) The option was granted January 29, 2010 and vests 25% annually for four years.
(3) The option was granted November 6, 2012 and vests 600,000 shares at grant date. The remaining shares will vest at the earlier of December 31, 2016 or when following events occur: 100,000 shares at enrollment of first patient in our dermaPACE clinical trial; 100,000 shares at enrollment of twentieth patient in the dermaPACE clinical trial; 100,000 shares at enrollment of fiftieth patient in the dermaPACE clinical trial; and 100,000 shares at FDA approval of the dermaPACE.
(4) The option was granted November 6, 2012 and vests 25% at grant date, 25% at three months, 25% at six months and 25% at nine months from the grant date.

Director Compensation Table for Fiscal 2012

Explanation of Responses:

We did not pay any director cash or stock-based compensation for serving on our board of directors during the fiscal year ended December 31, 2012. The following table provides certain information concerning compensation for each director during the fiscal year ended December 31, 2012.

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

(1) Ronald M. Sparks, Jr. and Barbara M. Henagan resigned from the Company's board on April 23, 2012. Thomas H. Robinson resigned from the Company's board on May 25, 2012. The three independent board members' did not receive any cash or stock-based compensation for serving on the board during 2012 and all outstanding options were forfeited unexercised.

Christopher M. Cashman, our former Chief Executive Office and President, who was a member of our board of directors until his resignation effective November 7, 2012, has been omitted from this table since he received no compensation for serving on our board of directors.

The following are the aggregate number of option awards outstanding that have been granted to each of our non-employee directors as of December 31, 2012: Kevin A. Richardson, II – 15,000 and John F. Nemelka – 15,000.

Discussion of Director Compensation

We did not pay any director cash or stock-based compensation for serving on our board of directors during the fiscal year ended December 31, 2012.

With the addition of former directors Barbara M. Henagan and Ronald M. Sparks, Jr. to the board of directors in September 2011, we began to compensate our three independent directors at an annual rate of $40,000 each plus $5,000 for being the chair of a board of directors committee. On September 20, 2011, we issued 25,000 options to purchase common stock at $2.95 to non-employee former director Ronald M. Sparks, Jr. On September 28, 2011, we issued 25,000 options to purchase common stock at $2.85 to non-employee former director Barbara M. Henagan. Ronald M. Sparks, Jr. and Barbara M. Henagan resigned from our board on April 23, 2012. Thomas H. Robinson resigned from our board on May 25, 2012. The three independent board members' did not receive any cash or stock-based compensation for serving on the board during 2012 and all outstanding options were forfeited unexercised.

Disclosure of Commission Position on Indemnification of Securities Act Liabilities

The Nevada General Corporation Law ("NGCL") provides that a director or officer is not individually liable to the corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his capacity as a director or officer unless (i) such act or omission constituted a breach of his/her fiduciary duties as a director or officer, and (ii) his/her breach of those duties involved intentional misconduct, fraud or a knowing violation of law. Under the NGCL, a corporation may indemnify directors and officers, as well as other employees and individuals, against any threatened, pending or completed action, suit or proceeding, except an action by or in the right of the corporation, by reason of the fact that he/she is or was a director, officer, employee or agent of the corporation so long as such person acted in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his/her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, does not, of itself, create a presumption that the person did not act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he/she had reasonable cause to believe that his/her conduct was unlawful.

The NGCL further provides that indemnification may not be made for any claim as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that, in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper. To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding or in defense of any claim, issue or matter therein, the corporation must indemnify him/her against expenses, including attorneys' fees, actually and reasonably incurred in connection with the defense. The NGCL provides that this is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders, or disinterested directors or

otherwise.

Explanation of Responses:

Our articles of incorporation provide that the directors and officers will not be personally liable to us or our stockholders for monetary damages for breach of their fiduciary duty as a director or officer, except for liability of a director or officer for acts or omissions involving intentional misconduct, fraud or a knowing violation of law, or the payment of dividends in violation of the NGCL. Our bylaws and contractual arrangements with certain of our directors and officers provide that we are required to indemnify our directors and officers to the fullest extent permitted by law. Our bylaws and these contractual arrangements also require us to advance expenses incurred by a director or officer in connection with the defense of any proceeding upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is ultimately determined by a court of competent jurisdiction that he/she is not entitled to be indemnified by the registrant. Our bylaws also permit us to purchase and maintain errors and omissions insurance on behalf of any director or officer for any liability arising out of his/her actions in a representative capacity. We do not presently maintain any such errors and omissions insurance for the benefit of our directors and officers.

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information, as of March 25, 2013, with respect to the beneficial ownership of our outstanding common stock by (i) any holder of more than five percent, (ii) each of our executive officers and directors, and (iii) our directors and executive officers as a group.

Name of Beneficial Owner (1)	Number of Shares Beneficially Owned (2)	Percent of Shares Outstanding	
Joseph Chiarelli (3)	375,000	1.7	%
Barry J. Jenkins (4)	480,003	2.2	%
Kevin A. Richardson, II (5)	1,778,837	8.1	%
John F. Nemelka (6)	38,833	*	
5% Beneficial Owner:			
David N. Nemelka (7)	5,048,510	19.7	%
Christopher M. Cashman (8)	3,936,259	15.7	%
Prides Capital Fund I, LP (9)	10,520,077	45.7	%
NightWatch Capital Partners II, LP (10)	2,108,369	9.7	%
All directors and executive officers as a group (4 persons)	2,672,673	11.8	%

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Explanation of Responses:

* Less than 1% of outstanding shares.
(1) Unless otherwise noted, each beneficial owner has the same address as us.
(2) Applicable percentage ownership is based on 21,580,536 shares of common stock outstanding as of March 25, 2013, "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of March 25, 2013. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.
(3) Consist of options to purchase up to 375,000 shares of common stock.
(4) Includes options to purchase up to 274,253 shares of common stock and warrants to purchase up to 3,508 shares of common stock.
(5) Includes options to purchase up to 38,333 shares of common stock and promissory notes convertible into 300,000 shares of common stock.
(6) Includes options to purchase up to 38,333 shares of common stock.
(7) Based solely on information contained in filings on Schedule 13D, as amended, and on Form 4's, made with the SEC by the reporting person. Includes a subscription agreement to purchase 3,600,000 shares of common stock at $0.25 per share no later than May 27, 2014 and warrants to purchase up to 443,510 shares of common stock. The principal address of David N. Nemelka is 2662 Stonebury Loop Road, Springville, UT 84663.
(8) Includes options to purchase up to 3,460,686 shares of common stock and warrants to purchase up to 8,816 shares of common stock. Mr. Cashman resigned as President, Chief Executive Officer, and as a Director effective November 7, 2012.
(9) Based solely on information contained in filings on Schedule 13D, as amended, made with the SEC by the reporting person. Includes warrants to purchase 1,438,088 shares of common stock. The principal business address of Prides Capital Fund, I, LP is 100 Cummings Center, Suite 324C, Beverly, MA 01915.
(10) Based solely on information contained in filings on Schedule 13D, as amended, made with the SEC by the reporting person. Includes warrants to purchase 204,224 shares of common stock. The principal business address of NightWatch Capital Partners II, LP is 5314 River Run Drive, Suite 350, Provo, UT 84604.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Party Transactions

Other than as described below, since January 1, 2010, there have been no transactions, and there are no currently proposed transactions with related persons required to be disclosed in this prospectus.

In connection with the offering of our Senior Secured Notes which closed on March 8, 2013, Kevin A. Richardson, II, chairman of the board of directors, purchased $60,000 of the notes.

On November 27, 2012, we and David N. Nemelka (Subscriber), the brother of John F. Nemelka, a member of our board of directors, entered into a subscription agreement (Subscription Agreement) whereby the Subscriber agreed to purchase from us, and we agreed to sell, a total of 4,000,000 shares of our common stock at a purchase price equal to $0.25 per share, for an aggregate sales price of $1,000,000 (Purchase Price). The Purchase Price will be payable to us as follows: (i) $50,000 on or before January 31, 2013; (ii) $50,000 on or before February 15, 2013; and (iii) the balance of $900,000 on or before May 27, 2014 (Outside Due Date). The Subscriber may make payments of the Purchase Price at his discretion, in minimum installments of $100,000 each, until the Outside Due Date. In the event that at any time after February 15, 2013, our total available cash should be less than $100,000, the Subscriber shall, upon our demand, pay to us $100,000 of the then outstanding balance of the Purchase Price, which payment shall be due within thirty (30) days of the demand. There is no limit on the number of demands that we may make pursuant to

this provision of the Subscription Agreement, provided, however, that in no event shall we provide more than one notice of demand for payment in any thirty (30) day period. As of December 31, 2012, the Subscriber had paid us $25,000 and we issued to the Subscriber 100,000 shares of common stock. We will record the additional $975,000 and issue the corresponding 3,900,000 shares of common stock in the periods in which the Purchase Price is received. Subsequent to December 31, 2012, the Subscriber has paid us an additional $75,000 and was issued an additional 300,000 shares of common stock which will be recorded in the first quarter of 2013.

On November 6, 2012, we entered into a Severance and Advisory Agreement (Severance Agreement) with Christopher M. Cashman, then a director of ours, and our President and Chief Executive Officer. Entry into the Severance Agreement was made in connection with Mr. Cashman's resignation as President and Chief Executive Officer, and a director of ours, effective November 7, 2012. See further discussion under "Management, Executive Compensation and Corporate Governance".

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

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

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

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

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

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 155,000,000 shares, of which 150,000,000 shares are designated as common stock and 5,000,000 shares are designated as preferred stock. As of March 25, 2013, there were issued and outstanding:

- 21,580,536 shares of common stock,
- warrants to purchase 7,789,991 shares of common stock at a weighted average exercise price of $3.63 per share, and
- options to purchase 8,604,330 shares of common stock at a weighted average exercise price of $1.14 per share.
- Senior Secured Notes with an aggregate principal and accrued interest balance of $2,067,500. Prior to commencement of the offering, we intend to have the Senior Secured 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.

The following summary of the material provisions of our common stock and preferred stock is qualified by reference to the provisions of our articles of incorporation and bylaws.

Common Stock

All shares of our common stock have equal voting rights and, when validly issued and outstanding, have one vote per share in all matters to be voted upon by the stockholders. Cumulative voting in the election of directors is not allowed, which means that the holders of more than 50% of the outstanding shares can elect all the directors if they choose to do so and, in such event, the holders of the remaining shares will not be able to elect any directors. The affirmative vote of a plurality of the shares of common stock voted at a stockholders meeting where a quorum is present is required to elect directors and to take other corporate actions. Holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds. However, the current policy of our board of directors is to retain earnings, if any, for our operation and expansion. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities and the liquidation preference of any outstanding preferred stock. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. All issued and outstanding shares of common stock are, and the common stock reserved for issuance upon exercise of our stock options and warrants will be, when issued, fully-paid

and non-assessable.

Explanation of Responses:

Preferred Stock

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

Warrants

The following is a brief summary of material provisions of the warrants offered in this offering. Such warrants will have the same material terms as the warrants we will issue we will issue to the holders of the Senior Secured Notes, if such notes are automatically converted to common stock as a result of this offering (which will occur if we raise at least $4,000,000 in this offering).

Exercise Price and Terms. Each warrant entitles the holder thereof to purchase at any time until _____, 20__, at a price of $_____ per share, subject to certain adjustments referred to below, shares of our common stock. The holder of any warrant may exercise such warrant by surrendering the warrant to us, with the notice of exercise properly completed and executed, together with payment of the exercise price. The warrants may be exercised at any time in whole or in part at the applicable exercise price until expiration of the warrants. No fractional shares will be issued upon the exercise of the warrants.

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

Transfer, Exchange and Exercise. The warrants may be presented to us for exchange or exercise at any time on or prior to _____, 20__, at which time the warrants become wholly void and of no value. Prior to any transfer of the warrants the holder must notify us of the same and, if subsequently requested, provide a legal opinion regarding the transfer to us.

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

18% Senior Secured Convertible Promissory Notes (Senior Secured Notes)

Prior to commencement of this offering, we intend to have the Senior Secured Notes amended to amend the conversion feature contained in such notes. Currently the Senior Secured Notes automatically convert to common stock (and warrants, if applicable) upon a qualified financing of $4,000,000 raised in a private placement transaction. We anticipate that the Senior Secured Notes will be amended to amend the definition of qualified financing to include a public offering of our common stock, which will then cover this offering. Therefore, upon completion of this offering where gross proceeds to us are at least $4,000,000, the Senior Secured Notes will automatically convert to common stock and warrants. We anticipate that this amendment to the Senior Secured Notes will be completed on or before April ___, 2013.

Anti-Takeover Provisions

Provisions in our Articles of Incorporation and bylaws may discourage certain types of transactions involving an actual or potential change of control of our Company which might be beneficial to us or our security holders.

As noted above, our Articles of Incorporation permits our board of directors to issue shares of any class or series of preferred stock in the future without stockholder approval and upon such terms as our board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Our bylaws generally provide that any board vacancy, including a vacancy resulting from an increase in the authorized number of directors, may be filled by a majority of the directors, even if less than a quorum.

Additionally, our bylaws provide that shareholders must provide timely notice in writing to bring business before an annual meeting of shareholders or to nominate candidates for election as directors at an annual meeting of shareholders. Notice for an annual meeting is timely if our Secretary receives the written notice not less man 50 days nor more than 75 days prior to the meeting; provided, however, that in the event less than 60 days notice or prior public disclosure of the date of the meeting is given or made to shareholders, notice by the shareholder to be timely must be so received not later than the close of business on the tenth day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made. Our bylaws also specify the form and content of a shareholder’s notice. These provisions may prevent shareholders from bringing matters before an annual meeting of shareholders or from making nominations for directors at an annual meeting of shareholders.

Trading Information

Our shares of common stock are currently quoted in the over-the-counter market on the OTC Bulletin Board.

Transfer Agent

The transfer agent and registrar for our common stock is Action Stock Transfer Corp., 7069 S. Highland Drive, Suite 300, Salt Lake City, Utah 84121.

SHARES AVAILABLE FOR FUTURE SALE

As of March 25, 2013, we had 21,580,536 shares of common stock outstanding, not including shares issuable upon the exercise of outstanding warrants, stock options and other convertible securities. Future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate. We cannot assure you that there will be an active market for our common stock.

Upon completion of this offering, and assuming 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 (which conversion will occur automatically only if we receive at least $4,000,000 in gross proceeds from this offering), based upon the number of shares outstanding at March 25, 2013, there will be _____ shares of our common stock outstanding. Of these outstanding shares, the _____ shares sold in this offering will be freely tradable without restriction or future registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales may be made only in compliance with the limitations of Rule 144 described below.

The remaining _____ shares outstanding after this offering are deemed "restricted securities" under Rule 144. Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which rules are summarized below, or another exemption. As a result of the provisions of Rule 144 and Rule 701, these restricted securities will be available for sale in the public market as follows:

Date of availability of sale	Approximate number of shares
90 days after the date of this prospectus	
180 days after the date of this prospectus, subject in some cases to applicable volume limitations under Rule 144	

Public Float

Of our outstanding shares at March 25, 2013, 14,063,637 shares are beneficially owned by executive officers, directors and affiliates of ours. The remaining 7,516,899 shares constitute our public float which, based on the last sale price of our common stock reported on the OTC Bulletin Board on _____, 2013, equaled approximately $____.

Rule 144

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

- 1% of the number of shares of our common stock then outstanding, which will equal approximately _____ shares of common stock immediately after consummation of this offering, or

- the average weekly trading volume of our common stock, assuming our shares are then traded on a national securities exchange, during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 are also subject to manner-of-sale provisions, notice requirements and the availability of current public information about us.

LEGAL MATTERS

The validity of the issuance of the securities offered by us in this offering will be passed upon for us by Smith, Gambrell & Russell, LLP, Atlanta, Georgia.

EXPERTS

The consolidated financial statements of SANUWAVE Health, Inc. as of December 31, 2012 and 2011 and for the years then ended included in this Prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

INTEREST OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis, or had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

SANUWAVE Health, Inc. and Subsidiaries

PART I — FINANCIAL INFORMATION

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of SANUWAVE Health, Inc. and Subsidiaries as of December 31, 2012 and 2011 and the related consolidated statements of comprehensive loss, stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of SANUWAVE Health, Inc. and Subsidiaries at December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ BDO USA, LLP

Atlanta, Georgia
March 26, 2013

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2012 and 2011

	2012	2011
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$70,325	$3,909,383
Accounts receivable - trade, net of allowance for doubtful accounts of $44,124 in 2012 and $74,852 in 2011	87,826	81,565
Inventory (Note 3)	292,665	396,284
Prepaid expenses	128,495	162,975
Due from Pulse Veterinary Technologies, LLC	-	27,837
TOTAL CURRENT ASSETS	579,311	4,578,044
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4)	32,842	51,206
OTHER ASSETS	11,358	3,192
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 5)	1,227,025	1,533,782
TOTAL ASSETS	$1,850,536	$6,166,224
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$555,898	$756,657
Accrued employee compensation	534,659	632,333
Accrued expenses (Note 6)	721,916	190,583
Subscriptions payable for senior secured convertible promissory notes (Note 7)	438,516	-
Interest payable, related parties (Note 8)	81,864	81,864
Capital lease payable, current portion (Note 13)	4,933	4,576
Liabilities related to discontinued operations (Note 9)	655,061	655,061
TOTAL CURRENT LIABILITIES	2,992,847	2,321,074
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 8)	5,372,743	5,372,743
Capital lease payable, non-current portion (Note 13)	3,951	8,884
TOTAL NON-CURRENT LIABILITIES	5,376,694	5,381,627
TOTAL LIABILITIES	8,369,541	7,702,701
COMMITMENTS AND CONTINGENCIES (Note 13)	-	-
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding (Note 11)	-	-
COMMON STOCK, par value $0.001, 150,000,000 shares and 50,000,000 shares authorized in 2012 and 2011, respectively; 21,007,536 and 20,907,536 issued and outstanding at December 31, 2012 and 2011, respectively (Note 11)	21,008	20,908

ADDITIONAL PAID-IN CAPITAL	64,357,193	62,940,977
ACCUMULATED OTHER COMPREHENSIVE INCOME	13,116	10,466
ACCUMULATED DEFICIT	(70,910,322)	(64,508,828)
TOTAL STOCKHOLDERS' DEFICIT	(6,519,005)	(1,536,477)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,850,536	$6,166,224

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
Years Ended December 31, 2012 and 2011

	2012	2011
REVENUES	$769,217	$802,572
COST OF REVENUES	220,257	261,890
GROSS PROFIT	548,960	540,682
OPERATING EXPENSES		
Research and development	1,762,194	2,731,059
General and administrative	4,521,957	6,292,950
Depreciation	20,375	19,034
Amortization	306,757	306,756
TOTAL OPERATING EXPENSES	6,611,283	9,349,799
OPERATING LOSS	(6,062,323)	(8,809,117)
OTHER INCOME (EXPENSE)		
Interest expense, net	(331,743)	(472,155)
Loss on foreign currency exchange	(7,428)	(13,744)
Transitional services provided to Pulse Veterinary Technologies, LLC	-	375,000
Loss on extinguishment of debt (Notes 8 and 11)	-	(1,318,781)
TOTAL OTHER INCOME (EXPENSE)	(339,171)	(1,429,680)
LOSS BEFORE INCOME TAXES	(6,401,494)	(10,238,797)
INCOME TAX EXPENSE	-	-
NET LOSS	(6,401,494)	(10,238,797)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	2,650	(436)
TOTAL COMPREHENSIVE LOSS	$(6,398,844)	$(10,239,233)
LOSS PER SHARE:		
Net loss - basic	$(0.30)	$(0.52)
Net loss - diluted	$(0.30)	$(0.52)
Weighted average shares outstanding - basic	20,915,869	19,624,061
Weighted average shares outstanding - diluted	20,915,869	19,624,061

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

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Years Ended December 31, 2012 and 2011

	Preferred Stock Shares Number of Issued and Outstanding	Par Value	Common Stock Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balances as of December 31, 2010	-	-	14,794,650	14,795	43,728,133	(54,270,031)	10,902	(10,516,201)
Unit options exercised for cash, related parties	-	-	1,231,504	1,231	2,461,777	-	-	2,463,008
Unit options exercised for cash	-	-	718,663	719	1,436,607	-	-	1,437,326
Private placement shares issued for cash	-	-	2,804,593	2,805	8,464,316	-	-	8,467,121
Notes payable, related parties exchanged for shares	-	-	1,358,126	1,358	5,731,331	-	-	5,732,689
Net loss	-	-	-	-	-	(10,238,797)	-	(10,238,797)
Stock-based compensation	-	-	-	-	1,118,813	-	-	1,118,813
Foreign currency translation adjustment	-	-	-	-	-	-	(436)	(436)
Balances as of December 31, 2011	-	-	20,907,536	20,908	62,940,977	(64,508,828)	10,466	(1,536,477)
Shares issued for cash	-	-	100,000	100	24,900	-	-	25,000
Net loss	-	-	-	-	-	(6,401,494)	-	(6,401,494)
Stock-based compensation	-	-	-	-	1,391,316	-	-	1,391,316
Foreign currency translation adjustment	-	-	-	-	-	-	2,650	2,650
Balances as of December 31, 2012	-	$-	21,007,536	$21,008	$64,357,193	$(70,910,322)	$ 13,116	$(6,519,005)

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

Explanation of Responses:

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Explanation of Responses:

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2012 and 2011

	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(6,401,494)	$(10,238,797)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization	306,757	306,756
Depreciation	20,375	19,034
Change in allowance for doubtful accounts	(30,728)	37,949
Stock-based compensation	1,391,316	1,118,813
Accrued interest on convertible notes	8,516	166,618
Loss on extinguishment of debt	-	1,318,781
Changes in assets - (increase)/decrease		
Accounts receivable - trade	24,467	(23,965)
Inventory	103,619	67,359
Prepaid expenses	34,480	(41,891)
Due from Pulse Veterinary Technologies, LLC	27,837	17,552
Other	(8,166)	29,061
Changes in liabilities - increase/(decrease)		
Accounts payable	(200,759)	(1,073,158)
Accrued employee compensation	(97,674)	(469,077)
Accrued expenses	531,333	(65,621)
Interest payable, related parties	-	(1,113)
NET CASH USED BY OPERATING ACTIVITIES	(4,290,121)	(8,831,699)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(2,011)	(42,302)
NET CASH USED BY INVESTING ACTIVITIES	(2,011)	(42,302)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from subscriptions payable for senior secured convertible promissory notes	430,000	-
Proceeds from sale of capital stock - subscription agreement with related party	25,000	-
Payments of principal on capital lease	(4,576)	(1,092)
Proceeds from unit options exercised, related parties	-	2,463,008
Proceeds from unit options exercised	-	1,437,326
Proceeds from private placement	-	8,467,121
NET CASH PROVIDED BY FINANCING ACTIVITIES	450,424	12,366,363
EFFECT OF EXCHANGE RATES ON CASH	2,650	(436)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,839,058)	3,491,926
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,909,383	417,457
CASH AND CASH EQUIVALENTS, END OF YEAR	$70,325	$3,909,383

Explanation of Responses:

SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$324,768	$324,768
Cash paid for capital lease interest	$858	$266
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Notes payable, related parties exchanged for capital stock (Note 8 and 11)	$-	$4,413,908
Equipment purchased with capital lease	-	14,552
TOTAL NON-CASH INVESTING AND FINANCING ACTIVITIES	$-	$4,428,460

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(1) Going Concern

As shown in the accompanying consolidated financial statements, the Company incurred a net loss of $6,401,494 and $10,238,797 during the years ended December 31, 2012 and 2011, respectively, and the net cash used by operating activities was $4,290,121 and $8,831,699, respectively. As of December 31, 2012, the Company had a net working capital deficit of $2,413,536, an accumulated deficit of $70,910,322 and cash and cash equivalents of $70,325. The operating losses and net working capital deficit create an uncertainty about the Company's ability to continue as a going concern.

The continuation of the Company's business is dependent upon raising additional capital. The Company has been working with select accredited investors to raise capital through issuing senior secured convertible promissory notes as discussed in Note (17). The Company received subscriptions for an aggregate $430,000 through December 31, 2012. Subsequent to year-end, the Company received subscriptions for an additional $1,570,000 in senior secured convertible promissory notes. The Company issued the aggregate $2,000,000 of senior secured convertible promissory notes on March 8, 2013. Kevin A. Richardson, II, chairman of the board of directors of the Company, purchased $60,000 of the senior secured convertible promissory notes. Management's plans are to obtain additional capital in 2013 through the issuance of common stock and/or other equities and has engaged an investment bank to assist with this capital raise.

Additionally, the Company may raise 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 by selling all or a portion of the Company's assets. If these efforts are unsuccessful, the Company 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 the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

(2) Summary of significant accounting policies

Description of the business – SANUWAVE Health, Inc. and subsidiaries (the "Company") is a shockwave technology company using noninvasive, high energy, acoustic shockwave for regenerative medicine and other applications. The Company's 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. The Company's lead product is the demaPACE device for treating diabetic foot ulcers which is in a supplemental Phase III clinical study with the FDA.

The Company's 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. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. The Company currently does not market any commercial products in the United States. Revenues are from sales of the European Conformity Marking ("CE Mark") devices and accessories in Europe, Canada and Asia.

In addition, there are license/partnership opportunities for the Company's shock wave technology in non-medical uses, including energy, water, food and industrial markets.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(2) Summary of significant accounting policies (continued)

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

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

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

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

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

Concentration of credit risk and limited suppliers - Management routinely assesses the financial strength of its customers and, as a consequence, believes accounts receivable are stated at the net realizable value and credit risk exposure is limited. Two distributors accounted for 29% and 20% of revenues for the year ended December 31, 2012, and 35% and 25% of revenues for the year ended December 31, 2011. The two distributors accounted for 35% and 6% of accounts receivable at December 31, 2012, and 23% and 29% of accounts receivable at December 31, 2011.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(2) Summary of significant accounting policies (continued)

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

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

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

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

Intangible assets - Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over the average life of 11.4 years. The Company regularly reviews intangible assets to determine if facts and circumstances indicate that the useful life is shorter than the Company originally estimated or that the carrying amount of the assets may not be recoverable. Factors the Company considers important and could trigger an impairment review include the following:

Significant delays or obstacles encountered in the dermaPACE device clinical trial and PMA application;

Significant changes in the manner in which we use our assets or significant changes in our overall business strategy; and

Significant underperformance of our assets relative to future operating results.

If such facts and circumstances exist, the Company assesses 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 its fair value.

Fair value of financial instruments - The book values of accounts receivable, accounts payable, and other financial instruments approximate their fair values, principally because of the short-term maturities of these instruments.

Explanation of Responses:

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(2) Summary of significant accounting policies (continued)

The Company has adopted ASC 820-10, Fair Value Measurements (formerly SFAS No. 157), which defines fair value, establishes a framework for measuring fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820-10 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 - Unobservable inputs that are not corroborated by market data, therefore requiring the Company to develop its own assumptions.

The Company’s notes payable, related parties consist of $5,372,743 of principal at December 31, 2012 and 2011. Interest accrues on the notes at a rate of six percent (6%) per annum. The fair value was determined using estimated future cash flows discounted at current rates, which is a Level 3 measurement. The estimated fair value of the Company’s notes payable, related parties was $4,545,620 and $4,253,362 at December 31, 2012 and 2011, respectively.

The Company’s subscriptions payable for the 18% senior secured convertible promissory notes consist of $438,516 in principal and accrued interest at December 31, 2012. Because of the short term nature of the subscription agreements and the underlying notes which have a maturity of six months and are not traded on an active market, the fair value is estimated to approximate the book value at December 31, 2012.

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

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

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

Explanation of Responses:

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(2) Summary of significant accounting policies (continued)

Income taxes - Income taxes are accounted for utilizing the asset and liability method prescribed by the provisions of ASC 740, Income Taxes (formerly SFAS No. 109, 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.

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

The Company will recognize in income tax expense interest and penalties related to income tax matters. For the years ended December 31, 2012 and 2011, the Company did not have any amounts recorded for interest and penalties.

Loss per share - The Company calculates net income (loss) per share in accordance with ASC 260, Earnings Per Share (formerly SFAS No. 128, Earnings Per Share). Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. To the extent that securities are "anti-dilutive," they are excluded from the calculation of diluted net income (loss) per share. As a result of the net loss for the years ended December 31, 2012 and 2011, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive equity securities totaled 15,162,069 shares and 14,390,697 shares at December 31, 2012 and 2011, respectively.

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

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

Explanation of Responses:

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(2) Summary of significant accounting policies (continued)

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

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

(3) Inventory

Inventory consists of the following at December 31, 2012 and 2011:

	2012	2011
Inventory - finished goods	$306,706	$412,291
Inventory - parts	83,509	113,593
Gross inventory	390,215	525,884
Provision for losses and obsolescence	(97,550)	(129,600)
Net inventory	$292,665	$396,284

(4) Property and equipment

Property and equipment consists of the following at December 31, 2012 and 2011:

	2012	2011
Machines and equipment	$ 233,793	$ 232,848
Office and computer equipment	179,349	224,600
Software	41,872	41,872
Furniture and fixtures	25,679	24,613
Vehicles	22,531	22,531
Leasehold improvements	-	67,421
Other assets	2,446	2,378
Total	505,670	616,263
Accumulated depreciation	(472,828)	(565,057)
Net property and equipment	$ 32,842	$ 51,206

The depreciation charged to operations was $20,375 and $19,034 for the years ended December 31, 2012 and 2011, respectively. The depreciation policies followed by the Company are described in Note (2).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(5) Intangible assets

Intangible assets consist of the following at December 31, 2012 and 2011:

	2012	2011
Patents, at cost	$3,502,135	$3,502,135
Less accumulated amortization	(2,275,110)	(1,968,353)
Net intangible assets	$1,227,025	$1,533,782

The amortization expense charged to operations was $306,757 and $306,756 for the years ended December 31, 2012 and 2011, respectively. The amortization policies followed by the Company are described in Note (2).

Amortization expense for the future years is summarized as follows:

Years ending December 31,	Amount
2013	$306,756
2014	306,756
2015	306,756
2016	306,757
Total	$1,227,025

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

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(6) Accrued expenses

Accrued expenses consist of the following at December 31, 2012 and 2011:

	2012	2011
Accrued executive severance	$542,269	$-
Accrued audit and tax preparation	102,600	75,516
Accrued legal professional fees	23,519	61,000
Accrued other	53,528	54,067
	$721,916	$190,583

On November 6, 2012, the Company entered into a Severance and Advisory Agreement (the “Severance Agreement”) with Christopher M. Cashman in connection with his resignation as President and Chief Executive Officer, and a director of the Company. Pursuant to the Severance Agreement, Mr. Cashman will receive, as severance along with other non-cash items, six months of his base salary payable over the following six month period and bonus payments of $100,000 upon each of four bonus payment events tied to the Company’s clinical trial plan for the dermaPACE device, or December 31, 2016, whichever occurs first. The accrued executive severance at December 31, 2012 represents the unpaid portion of the base salary and bonus payments.

(7) Subscriptions payable for senior secured convertible promissory notes

During the year ended December 31, 2012, the Company entered subscriptions payable for 18% senior secured convertible promissory notes (the “Senior Secured Notes”) from selected accredited investors. Up to $2,000,000 aggregate principal amount of Senior Secured Notes are being offered (the “Offering”) by the Company. The Company completed the Offering and issued an aggregate $2,000,000 in notes on March 8, 2013.

The Senior Secured Notes have a six month term from the subscription date and the note holders can convert into Company common stock at anytime during the term at $0.20 per share. Upon the consummation of a qualified financing and/or technology license, as defined in the Senior Secured Note agreements, of $4,000,000 or more by the Company, the principal and interest on the Senior Secured Notes will convert into Company common stock equal to the lower of (i) the Company common stock issued in the qualified financing and/or technology license, reduced by a discount of 20%, and (ii) $0.20 per share. The 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 the tangible and intangible assets of the Company. The Company is in the process of evaluating the accounting treatment for these notes issued subsequent to December 31, 2012 and any potential embedded derivatives included therein.

As of December 31, 2012, the Company had received subscriptions payable for Senior Secured Notes in the aggregate principal amount of $430,000 and had accrued interest expense of $8,516.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(8) Notes payable, related parties

The notes payable, related parties consist of the following at December 31, 2012 and 2011:

	2012	2011
Notes payable, unsecured, payable to HealthTronics, Inc., a shareholder of the Company	$5,372,743	$5,372,743
Less current portion	-	-
Non-current portion	$5,372,743	$5,372,743

The notes payable, related parties were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. The notes payable, related parties bear interest at 6% per annum. 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 currently payable totaled $81,864 at December 31, 2012 and 2011. Accrued interest not payable until August 1, 2015 totaled $1,372,743 at December 31, 2012 and 2011, and is included in the balance above.

Maturities on notes payable, related parties are as follows:

Years ending December 31,	Amount
2013	$-
2014	-
2015	5,372,743
Total	$5,372,743

On April 4, 2011, the Company amended the terms of outstanding notes with Prides Capital Fund I, LP and NightWatch Capital Partners II, LP such that the unpaid principal and interest balance on the notes, totaling $4,413,908, was cancelled in consideration of the issuance of 1,358,126 shares of common stock of the Company. In addition, the Company, in connection with this transaction, 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. In accordance with ASC 470, "Debt", in April 2011, the Company 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 of $9,330,326 and the fair value of the notes (assuming the conversion feature was exercised by the noteholders) of $8,011,545.

Interest expense on notes payable, related parties totaled $324,768 and $490,273 for the years ended December 31, 2012 and 2011, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(9) Discontinued operations

As of December 31, 2012 and 2011, the Company's liabilities related to discontinued operations were as follows:

	2012	2011
Accrued expenses	$(655,061)	$(655,061)
Liabilities of discontinued operations	$(655,061)	$(655,061)

(10) Income taxes

The Company files income tax returns in the United States federal jurisdiction and various state and foreign jurisdictions. The Company is no longer subject to United States federal and state and non-United States income tax examinations by tax authorities for years before 2006.

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

The income tax provision (benefit) consists of the following at December 31, 2012 and 2011:

	2012	2011
Current:		
Federal	$-	$-
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	(2,126,006)	(2,885,054)
State	(227,883)	(332,175)
Foreign	12,556	52,136
Change in valuation allowance	2,341,333	3,165,093
	$-	$-

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(10) Income taxes (continued)

The income tax provision (benefit) amounts differ from the amounts computed by applying the United States federal statutory income tax rate of 34% to pretax income (loss) as a result of the following for the years ended December 31, 2012 and 2011:

	2012	2011
Tax expense (benefit) at statutory rate	$(2,176,508)	$(3,583,579)
Increase (reduction) in income taxes resulting from:		
State income taxes (benefit), net of federal benefit	(159,432)	(248,639)
Income from foreign subsidiaries	165,660	461,573
Non-deductible loss on extinguishment of debt	-	216,969
Change in valuation allowance - United States	2,301,986	3,217,229
Other	(131,706)	(63,553)
Income tax expense (benefit)	$-	$-

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2012 and 2011 are as follows:

	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$20,147,348	$18,458,402
Net operating loss carryforwards - foreign	148,674	109,327
Excess of tax basis over book value of property and equipment	42,946	63,785
Excess of tax basis over book value of intangible assets	431,513	427,484
Stock-based compensation	3,097,308	2,572,287
Accrued employee compensation	352,032	235,109
Captialized equity costs	75,471	75,471
Inventory reserve	36,811	48,905
	24,332,103	21,990,770
Valuation allowance	(24,332,103)	(21,990,770)
Net deferred tax assets	$-	$-

The Company’s ability to use its net operating loss carryforwards could be limited and subject to annual limitations. In connection with future offerings, the Company may realize a “more than 50% change in ownership” which could further limit its ability to use its 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, the Company may not be able to take advantage of all or portions of its net operating loss carryforwards for federal income tax purposes.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(10) Income taxes (continued)

The federal net operating loss carryforwards at December 31, 2012 will expire as follows:

Years ending December 31,	Amount
2025	$1,376,740
2026	7,291,084
2027	12,280,771
2028	6,922,963
2029	4,816,700
2030	7,667,557
2031	8,816,976
2032	4,844,424
Total	$54,017,215

(11) Equity Transactions

Private placement and note exchange

On April 8, 2011, the Company completed a private placement to 28 institutional and individual “accredited investors” (as that term is defined in the Rule 501 under the Securities Act of 1933, as amended (the “Securities Act”)) of 2,804,593 shares of common stock of the Company at a purchase price of $3.25 per share, for gross proceeds of $9,114,927. The net proceeds received by the Company were $8,467,121, net of offering costs of $647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of common stock at an exercise price of $4.00 per share. In addition, the placement agent for the private placement was issued a five-year warrant 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.

For each of the warrants, the holder will be able to exercise the warrant on a so-called cashless basis at any time following the one-year anniversary of the closing of the private placement if a registration statement covering the shares of common stock underlying such warrants is not effective. The Company filed a registration statement with respect to the resale of the shares of common stock sold to the investors and shares of common stock issuable upon exercise ofthe warrants with the SEC and kept the registration statement effective until all registrable securities were sold or may be sold pursuant to Rule 144 under the Securities Act. The registration statement is no longer effective as the shares have been held for over one year and the Company believes that the shares may be sold pursuant to Rule 144 under the Securities Act.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(11) Equity Transactions (continued)

On April 4, 2011, Prides Capital Fund I, LP and NightWatch Capital Partners II, LP (the "Noteholders"), holders of certain notes payable (the "Notes") and related parties of the Company, 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, the Company 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. Each warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expire after five years. In accordance with ASC 470, "Debt", in April 2011, the Company 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 of $9,330,326 and the fair value of the Notes (assuming the conversion feature was exercised by the Noteholders) of $8,011,545.

Unit options

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

Preferred stock

The Company's preferred stock may have such rights, preferences and designations and may be issued in such series as determined by the board of directors. No shares were issued and outstanding at December 31, 2012 and 2011.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2012 and 2011

(12) Warrants

A summary of warrants as of December 31, 2012 and 2011, and the changes during the years ended December 31, 2012 and 2011, is presented as follows:

	Class A Warrants	Class B Warrants	Class D Warrants	Class E Warrants
Outstanding as of December 31, 2010	1,106,627	1,106,627	2,284,993	-
Issued	-	-	1,950,167	3,576,737
Exercised	-	-	-	-
Expired	-	-	-	-
Outstanding as of December 31, 2011	1,106,627	1,106,627	4,235,160	3,576,737
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	(2,284,993)	-
Outstanding as of December 31, 2012	1,106,627	1,106,627	1,950,167	3,576,737

The Class A, Class B and Class E Warrants expire five years from date of issuance and the Class D warrants expire two years from date of issuance. The outstanding Class D Warrants at December 31, 2012 expired unexercised on January 31, 2013.

The Class A and Class E warrants have an exercise price of $4.00 per share, the Class B warrants have an exercise price of $8.00 per share, and the Class D warrants have an exercise price of $2.00 per share. The exercise price and the number of shares covered by the warrants will be adjusted if the Company has a stock split, if there is a recapitalization of the Company's common stock, or if the Company consolidates with or merges into another corporation.

(13) Commitments and contingencies

Subscription agreement

On November 27, 2012, the Company and David N. Nemelka (the "Subscriber"), the brother of John F. Nemelka, a member of the Company's board of directors, entered into a subscription agreement (the "Subscription Agreement") whereby the Subscriber has agreed to purchase from the Company, and the Company has agreed to sell and issue, a total of 4,000,000 shares of the Company's unregistered common stock at a purchase price equal to $0.25 per share, for an aggregate sales price of $1,000,000 (the "Purchase Price"). The shares are subject to piggy-back registration rights if the Company files a registration statement for an offering of securities.

The Purchase Price shall be payable to the Company as follows: (i) $50,000 on or before January 31, 2013; (ii) $50,000 on or before February 15, 2013; and (iii) the balance of $900,000 on or before May 27, 2014 (the "Outside Due Date"). The Subscriber may make payments of the Purchase Price at his discretion in minimum installments of $100,000 each, until the Outside Due Date.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(13) Commitments and contingencies (continued)

In the event that at any time after February 15, 2013, the Company's total available cash should be less than $100,000, the Subscriber shall, upon demand of the Company, pay to the Company $100,000 of the then outstanding balance of the Purchase Price, which payment shall be due within thirty (30) days of the demand. There is no limit on the number of demands that the Company may make pursuant to this provision of the Subscription Agreement, provided, however, that in no event shall the Company provide more than one notice of demand for payment in any thirty (30) day period.

As of December 31, 2012, the Subscriber had paid the Company $25,000 and was issued 100,000 shares of unregistered common stock of the Company. The Company will record the additional $975,000 and issue the corresponding 3,900,000 shares of common stock in the periods in which the Purchase Price is received. Subsequent to December 31, 2012, the Subscriber has paid the Company an additional $75,000 and was issued an additional 300,000 shares of unregistered common stock of the Company which was recorded in the first quarter of 2013.

Operating Leases

The Company leases office and warehouse space. Rent expense for the years ended December 31, 2012 and 2011, was $298,452 and $361,189, respectively. Minimum future lease payments under non-cancellable operating leases consist of the following:

Year ending December 31,	Amount
2013	$102,576
2014	105,643
2015	90,225
Total	$298,444

Capital Leases

The Company leases certain office equipment under an agreement classified as a capital lease. The leased assets serve as security for the lease. The accumulated depreciation of such equipment at December 31, 2012 and 2011 totaled $6,468 and $1,617, respectively. The net book value of such equipment at December 31, 2012 and 2011 totaled $8,085 and $12,935, respectively.

The future commitments as of December 31, 2012 under this capital lease agreement are as follows:

Year ending December 31,	Principal	Interest	Total
2013	$4,933	$501	$5,434
2014	3,951	125	4,076
	$8,884	$626	$9,510

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(13) Commitments and contingencies (continued)

Litigation

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

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

(14) 401(k) plan

The Company sponsors a 401(k) plan that covers all employees who meet the eligibility requirements. The Company matched 50% of employee contributions up to 6% of theircompensation effective until January 31, 2012. Effective February 1, 2012, the Company amended the 401(k) plan to make the Company matching contribution discretionary and discontinued the Company match. The Company contributed $9,664 and $73,797 to the plan for the years ended December 31, 2012 and 2011, respectively.

(15) Stock-based compensation

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the “Stock Incentive Plan”). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is currently administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to four years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At December 31, 2012, the Stock Incentive Plan reserved 5,000,000 shares of common stock for grant. Subsequent to December 31, 2012, the Stock Incentive Plan was amended to reserve a total of 8,500,000 shares of common stock for grant.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(15) Stock-based compensation (continued)

As discussed in Note (6), on November 6, 2012, the Company entered into a Severance Agreement with Christopher M. Cashman in connection with his resignation as President and Chief Executive Officer, and a director of the Company. Pursuant to the Severance Agreement, Mr. Cashman received (a) a grant of 1,000,000 options to acquire shares of common stock at an exercise price of $0.21 per share with 600,000 of the options vested upon the execution of the Severance Agreement and the remaining 400,000 options vesting in increments of 100,000 upon events tied to the Company's clinical trial plan for the dermaPACE device, or December 31, 2016, whichever occurs first, (b) a grant of 50,000 options to acquire shares of common stock at an exercise price of $0.21 per share as consideration for the provision of twelve months of advisory services and (c) the full vesting of all other outstanding and unvested options. Using the Black-Scholes option pricing model, management has determined that the options granted in November 2012 had a fair value per share of $0.15 resulting in total compensation of $160,500. Compensation cost will be recognized over the requisite vesting period.

On March 8, 2012, the Company granted two members of the Company's Medical Advisory Board each options to purchase 50,000 shares of the Company's common stock at an exercise price of $0.44 per share in place of an annual cash consulting fee. Using the Black-Scholes option pricing model, management has determined that the options granted in March 2012 had a fair value per share of $0.27 resulting in total compensation of $27,250. Compensation cost was recognized over the calendar year 2012.

On November 16, 2011, the Company granted an employee options to purchase 25,000 shares of the Company's common stock at an exercise price of $1.60 per share. Using the Black-Scholes option pricing model, management has determined that the options granted in November 2011 had a fair value per share of $0.96 resulting in total compensation of $24,000. Compensation cost will be recognized over the requisite service period.

On October 24, 2011, the Company granted 1,300,000 options to an employee at an exercise price of $1.98 per share. Using the Black-Scholes option pricing model, management has determined that the options granted in October 2011 had a fair value per share of $1.15 resulting in total compensation of $1,496,563. Compensation cost will be recognized over the requisite service period.

On September 28, 2011, the Company granted 25,000 options to a member of the board of directors at an exercise price of $2.85 per share. On September 20, 2011, the Company granted 25,000 options to a member of the board of directors at an exercise price of $2.95 per share. Using the Black-Scholes option pricing model, management has determined that the options granted in September 2011 had a weighted average fair value per share of $1.58 resulting in total compensation of $78,750. The stock options were fully vested when granted and therefore the full compensation cost was recognized at grant date.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(15) Stock-based compensation (continued)

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the years ended December 31, 2012 and 2011:

	2012		2011	
Weighted average expected life in years	5.2		5.8	
Weighted average risk free interest rate	0.81	%	1.32	%
Weighted average volatility	97.83	%	65.00	%
Forfeiture rate	0.0	%	0.0	%
Expected dividend yield	0.0	%	0.0	%

Since there is a limited trading history for our common stock, the expected volatility is based on historical data from companies similar in size and value to us. The expected dividend yield is based on our historical dividend experience, however, since our inception, we have not declared dividends. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. We estimate pre-vesting forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest. The expected life of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted.

For the years ended December 31, 2012 and 2011, the Company recognized $1,391,316 and $1,118,813, respectively, as compensation cost related to options granted. The remaining $87,184 of compensation cost will be recognized over the next three years as follows:

Years ending December 31,	Unrecognized Compensation Cost
2013	$78,260
2014	7,542
2015	1,382
Total	$87,184

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(15) Stock-based compensation (continued)

A summary of option activity as of December 31, 2012 and 2011, and the changes during the years ended December 31, 2012 and 2011, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2010	2,992,796	$3.20
Granted	1,375,000	$2.00
Exercised	-	$-
Forfeited or expired	(2,250)	$3.14
Outstanding as of December 31, 2011	4,365,546	$2.82
Granted	1,150,000	$0.23
Exercised	-	$-
Forfeited or expired	(286,216)	$2.85
Outstanding as of December 31, 2012	5,229,330	$2.25
Exercisable	4,720,580	$2.42

The weighted average remaining contractual term for outstanding exercisable stock options is 6.6 years as of December 31, 2012 and 6.3 years as of December 31, 2011.

A summary of the Company’s nonvested options as of December 31, 2012 and 2011, and changes during the years ended December 31, 2012 and 2011, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2010	883,993	$4.69
Granted	1,375,000	$2.01
Vested	(943,084)	$3.85
Forfeited or expired	(1,187)	$3.62
Outstanding as of December 31, 2011	1,314,722	$2.48
Granted	1,150,000	$0.23
Vested	(1,901,722)	$1.52
Forfeited or expired	(54,250)	$3.41
Outstanding as of December 31, 2012	508,750	$0.66

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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(16) Segment and geographic information

The Company has one line of business with revenues being generated from sales in Europe and Asia and all significant expenses being generated in the United States. All significant assets are located in the United States.

(17) Subsequent events

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

Senior Secured Notes
The Company has been working with select accredited investors to raise capital through the issuance of Senior Secured Notes as discussed in Note (7). Through December 31, 2012, the Company had received subscriptions payable for Senior Secured Notes in the aggregate principal amount of $430,000 and had accrued interest expense of $8,516. Up to $2,000,000 aggregate principal amount of Senior Secured Notes are being offered by the Company.

Subsequent to year-end, the Company received an additional $1,570,000 in subscriptions for the Senior Secured Notes. The Company completed the offering on March 8, 2013 and issued such notes. Kevin A. Richardson, II, chairman of the board of directors of the Company, purchased $60,000 of the Senior Secured Notes.

Subscription Agreement
As discussed in Note (13), on November 27, 2012, the Company entered into a Subscription Agreement whereby the Subscriber has agreed to purchase from the Company, and the Company agreed to sell and issue, a total of 4,000,000 shares of the Company’s unregistered common stock at a purchase price equal to $0.25 per share, for an aggregate sales price of $1,000,000. As of December 31, 2012, the Subscriber had paid the Company $25,000 and was issued 100,000 unregistered shares of common stock of the Company. The Company will record the additional $975,000 and issue the corresponding 3,900,000 shares of common stock in the periods in which the Purchase Price is received.

Subsequent to December 31, 2012, the Subscriber has paid the Company an additional $75,000 and was issued an additional 300,000 shares of unregistered common stock of the Company which was recorded in the first quarter of 2013.

2013 Additional Capital Raise and Consulting Agreements
The continuation of the Company’s business is dependent upon raising additional capital. Management’s plans are to obtain additional capital in 2013 through the issuance of common stock or other equities. The Company has engaged financial advisors to identify the opportunities for a capital raise to fund the Company's dermaPACE clinical work and provide working capital. The Company has issued to a consultant, 2,000,000 warrants to purchase the Company’s common stock at $0.35 per share. The four year warrants vest 300,000 on the date of grant and 1,700,000 upon the completion of a $5,000,000, or greater, capital raise.

In February 2013, the Company entered into a consulting agreement with a consultant to assist the Company with its strategy for raising additional capital for which a portion of the fee for the services performed is common stock and warrants. The Company issued 100,000 shares of common stock under this agreement in February 2013. In addition, the Company will issue to the consultant 1,000,000 warrants to purchase common stock at an exercise price of $0.35 per share with a term of five years upon consummation by the Company of an qualified offering (as defined

in the consulting agreement) resulting in gross proceeds to the Company of no less than $4,000,000.

In February 2013, the Company entered into two consulting agreements for which a portion of the fee for the services performed is paid with common stock. The Company has issued 173,000 shares of common stock under these agreements through March 22, 2013.

Employment Agreement with new Chief Executive Officer

Subsequent to December 31, 2012, Joseph Chiarelli joined the Company to serve as the Chief Executive Officer and a director of the Company commencing on February 25, 2013 with a two year term thereafter extendable for one year periods. Mr. Chiarelli is entitled to an annual base salary of $200,000 for the first year and $225,000 thereafter, with a performance and compensation review not less often than annually, at which time compensation may be adjusted as determined by the board of directors.

In the event of the satisfaction of the following milestones, the Company shall award and pay to Mr. Chiarelli a cash bonus as follows: (i) $35,000 for the Company completing a financing resulting in gross proceeds to the Company of no less than $5,000,000 at a price per share of not less than $0.35; (ii) $25,000 when the final patient is enrolled in the Company's dermaPACE Phase III clinical trial; (iii) $25,000 upon receipt by the Company of FDA approval for the use of dermaPACE; and (iv) $25,000 upon the execution by the Company of a license or distribution agreement from which the Company is entitled to receive gross proceeds of no less than $1,000,000 and the Company has received payments of at least $250,000. In addition, with respect to each full fiscal year, Mr. Chiarelli is eligible to earn an annual bonus award as determined by the board of directors based on the achievement of certain performance goals established by the board of directors. Mr. Chiarelli is also entitled to participate in the Company's employee benefit plans (other than annual bonus and incentive plans). The employment agreement contains an agreement not to compete, which covers the term of employment and two years thereafter, and a confidentiality provision, which is indefinite.

Upon the execution of his employment agreement, Mr. Chiarelli was granted options to purchase 2,250,000 shares of the Company's common stock at an exercise price of $0.35 per share. The options vest and become exercisable in five installments as follows: (i) 375,000 vested at grant; (ii) 375,000 vest upon the Company completing a financing resulting in gross proceeds to the Company of no less than $5,000,000 at a price per share of not less than $0.35; (iii) 375,000 upon the execution by the Company of a license or distribution agreement from which the Company is entitled to receive gross proceeds of no less than $1,000,000 and the Company has received payments of at least $250,000; (iv) 375,000 vest upon receipt by the Company of FDA approval for the use of dermaPACE; and (v) 750,000 vest in the event the Company achieves the milestones (i), (ii), (iii) and (iv) above during the initial two year term and the term is not extended by the Company.

Stock Incentive Plan

Subsequent to December 31, 2012, the Company amended the Stock Incentive Plan to increase the shares of common stock reserved for grant pursuant to the Stock Incentive Plan to 8,500,000. In addition, on February 21, 2013, the Company, by mutual agreement with the active employees and directors of the Company, cancelled options granted to the active employees in the year ended December 31, 2011 and prior which totaled 1,113,644 shares of common stock at an average exercise price of $2.92. In exchange for these options, the active employees and directors received new options to purchase 2,243,644 shares of common stock at an exercise price of $0.35 per share. The Company will record the effect of this transaction in the first quarter of 2013.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. Other Expenses of Issuance and Distribution

The following table lists the costs and expenses payable by the registrant in connection with the sale of the common stock covered by this. All amounts shown are estimates except for the SEC registration fee.

SEC registration fee	$818.40
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous fees and expenses	*
Total	$*

* To be completed by amendment.

ITEM 14. Indemnification of Directors and Officers

The Nevada General Corporation Law ("NGCL") provides that a director or officer is not individually liable to the corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his capacity as a director or officer unless (i) such act or omission constituted a breach of his/her fiduciary duties as a director or officer, and (ii) his/her breach of those duties involved intentional misconduct, fraud or a knowing violation of law. Under the NGCL, a corporation may indemnify directors and officers, as well as other employees and individuals, against any threatened, pending or completed action, suit or proceeding, except an action by or in the right of the corporation, by reason of the fact that he/she is or was a director, officer, employee or agent of the corporation so long as such person acted in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his/her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, does not, of itself, create a presumption that the person did not act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he/she had reasonable cause to believe that his/her conduct was unlawful.

The NGCL further provides that indemnification may not be made for any claim as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that, in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper. To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding or in defense of any claim, issue or matter therein, the corporation must indemnify him/her against expenses, including attorneys' fees, actually and reasonably incurred in connection with the defense. The NGCL provides that this is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders, or disinterested directors or otherwise.

The registrant's articles of incorporation provide that the directors and officers will not be personally liable to the registrant or its stockholders for monetary damages for breach of their fiduciary duty as a director or officer, except for liability of a director or officer for acts or omissions involving intentional misconduct, fraud or a knowing violation of law, or the payment of dividends in violation of the NGCL. The registrant's bylaws and contractual arrangements with certain of its directors and officers provide that the registrant is required to indemnify its directors and officers to the fullest extent permitted by law. The registrant's bylaws and these contractual arrangements also require the registrant to advance expenses incurred by a director or officer in connection with the defense of any proceeding upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is ultimately determined by a court of competent jurisdiction that he/she is not entitled to be indemnified by the registrant. The registrant's bylaws also permit the registrant to purchase and maintain errors and omissions insurance on behalf of any director or officer for any liability arising out of his/her actions in a representative capacity. The registrant does not presently maintain any such errors and omissions insurance for the benefit of its directors and officers.

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

ITEM 15. Recent Sales of Unregistered Securities

On November 27, 2012, we entered into a subscription agreement (Subscription Agreement) with David N. Nemelka (Subscriber), the brother of John F. Nemelka, a member of our board of directors, whereby the Subscriber agreed to purchase from us, and us agreed to sell and issue, a total of 4,000,000 shares of our common stock, at a purchase price equal to $0.25 per share, for an aggregate sales price of $1,000,000. These shares were sold pursuant to the exemption provided by the SEC's Rule 506 of Regulation D under the Securities Act.

In February 2013, we entered into two consulting agreements for which a portion of the fee for the services performed is paid with common stock. We have issued 173,000 shares of common stock under these agreements through March 25, 2013.

In February 2013, we entered into a consulting agreement with a consultant to assist us with our strategy for raising additional capital for which a portion of the fee for the services performed is common stock and warrants. We issued 100,000 shares of common stock under this agreement in February 2013. In addition, we will issue to the consultant 1,000,000 warrants to purchase common stock at an exercise price of $0.35 per share with a term of five years upon consummation by us of an qualified offering (as defined in the consulting agreement) resulting in gross proceeds to us of no less than $4,000,000.

In February 2013, we entered into a consulting agreement with a consultant to assist us with our strategy for raising additional capital for which the fee for the services performed was paid with warrants. We have issued to the consultant 2,000,000 warrants to purchase common stock at an exercise price of $0.35 per share with a term of five years. The warrants vest 300,000 upon grant and 1,700,000 upon consummation of an offering of securities managed by an investment bank resulting in gross proceeds to us of no less than $5,000,000 on or prior to June 1, 2013.

In connection with the foregoing, we relied upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

On April 8, 2011, pursuant to the exemptive provision of Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder, we completed a private placement to 28 institutional and individual accredited investors of 2,804,593 shares of our common stock at a purchase price of $3.25 per share, for gross proceeds to us 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 our common stock at an initial exercise price of $4.00 per share. The net proceeds from the private placement, following the payment of offering-related expenses, are being used by us for working capital and other general corporate purposes. David N. Nemelka, the brother of John F. Nemelka, a member of our board of directors, and an existing shareholder of ours, was one of the purchasers in the offering.

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

In January 2011, pursuant to the exemptive provision of Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder, we issued1,950,167 shares of common stock for gross proceeds of $3,900,334 from a group of accredited investors upon the exercise of options we issued in 2010 as part of the sale of Units consisting 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, which, as amended, expired on January 31, 2011, to purchase the same number of units as granted pursuant to this transaction, at the purchase price of $2.00 per unit. Kevin A Richardson, II, the chairman of the our board of directors exercised 545,252 options and David N. Nemelka, the brother of John F. Nemelka, a member of our board of directors, exercised 686,252 options in connection with this transaction.

On September 30, 2010, pursuant to the exemptive provision of Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder, we completed a private placement to individual accredited investors. We issued 150,000 Units for an aggregate total purchase price of $300,000. On October 1, 2010, November 19, 2010, and December 7, 2010 in conjunction with offerings of securities by us under the Securities Act, we issued 250,000, 142,500 and 382,500 Units to individual accredited investors for $500,000, $285,000 and $765,000, respectively. Each Unit was sold to the new investors at a purchase price of $2.00 per Unit. As a result of the offerings, we sold 925,000 Units which consisted of 925,000 shares of common stock, 925,000 Class D Warrants and 925,000 Options. David N. Nemelka, the brother of John F. Nemelka, a member of our board of directors, purchased 175,000 Units in the offerings for a total purchase price of $350,000.

As of December 31, 2010, the Option holders exercised 101,163 Options for total gross proceeds of $202,326. In connection with the exercise of the Options, we issued 101,163 shares of common stock and 101,163 Class D Warrants.

During the year ended December 31, 2010, we issued ten promissory notes to accredited investors in the aggregate amount of $2,450,000. On October 12, 2010, pursuant to the exemptive provision of Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder, we amended the terms of the ten outstanding promissory notes such that the unpaid principal and interest on each note was exchanged into the number of Units equal to (i) the unpaid principal and interest on each such note, divided by (ii) 2. The unpaid principal and interest on the notes in the

aggregate amount of $2,517,660 were exchanged for an aggregate of 1,258,830 Units which consisted of 1,258,830 shares of common stock, 1,258,830 Class D Warrants and 1,258,830 Options. Kevin A. Richardson, II, our chairman of the board of directors exchanged promissory notes totaling $1,790,504 and David N. Nemelka, the brother of John F. Nemelka, a member of our board of directors, exchanged promissory notes in the aggregate amount of $522,504.

ITEM 16. Exhibits and Financial Statement Schedules

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).
3.4	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
4.1	Form of Class A Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.2	Form of Class B Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.3	Form of Class D Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on October 14, 2010).
4.4	Form of Class E Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011)
4.5	Form of 18% Senior Secured Convertible Promissory Note issued by SANUWAVE Health, Inc. to select accredited investors (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).
4.6**	Form of Warrant
5.1**	Opinion of Smith, Gambrell & Russell, LLP.
10.1	Employment Agreement, dated December 19, 2005, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.2	First Amendment to Employment Agreement, dated September 15, 2009, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
10.3	Amendment to Nonstatutory Stock Option Award and Nonstatutory Supplemental Agreements, dated September 15, 2009, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management

compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

10.4 Employment Agreement, dated April 10, 2006, by and between SANUWAVE, Inc. and Barry J. Jenkins. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

10.5 Amendment to Nonstatutory Stock Option Award and Nonstatutory Supplemental Agreements, dated September 15, 2009, by and between SANUWAVE, Inc. and Barry J. Jenkins. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

10.6 Management Stockholders Agreement, dated as of December 19, 2005, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

10.7 Amendment to Management Stockholders Agreement, dated as of October 24, 2006, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

10.8 Second Amendment to Management Stockholders Agreement, dated as of September 25, 2009, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).

10.9 Amended and Restated 2006 Stock Option Incentive Plan of SANUWAVE Health, Inc. (Incorporated by reference to Form 8-K filed with the SEC on November 3, 2010).

10.10 Form of Securities Purchase Agreement, by and between the Company and the accredited investors party thereto, dated April 4, 2011 (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).

10.11 Form of Registration Rights Agreement, by and between the Company and the holders party thereto, dated April 4, 2011 (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).

10.12 Agreement between Prides Capital Fund I, LP and SANUWAVE Health, Inc., dated April 4, 2011 (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).

10.13 Agreement between NightWatch Capital Partners II, LP and SANUWAVE Health, Inc., dated April 4, 2011 (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).

10.14 Severance and Advisory Agreement, dated November 6, 2012, by and between SANUWAVE Health, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on November 13, 2012).

10.15 Subscription Agreement, dated November 27, 2012, by and between SANUWAVE Health, Inc. and David N. Nemelka (Incorporated by reference to Form 8-K filed with the SEC on December 3, 2012).

10.16 Employment Agreement, dated February 21, 2013, by and between SANUWAVE Health, Inc. and Joseph Chiarelli (Management compensation plan or arrangement) (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).

10.17** Form of Securities Purchase Agreement

21.1* List of subsidiaries.

23.1** Consent of Smith, Gambrell & Russell, LLP (included in its opinion filed as Exhibit 5.1 hereto).

23.2* Consent of BDO USA, LLP, independent registered public accountants.

24.1* Power of Attorney (set forth on the signature page of this registration statement).

Explanation of Responses:

101.INS*** XBRL Instance

101.SCH*** XBRL Taxonomy Extension Schema

101.CAL*** XBRL Taxonomy Extension Calculation

101.DEF*** XBRL Taxonomy Extension Definition

101.LAB*** XBRL Taxonomy Extension Labels

101.PRE*** XBRL Taxonomy Extension Presentation

* Filed Herewith
** To be filed by amendment.
*** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

ITEM 17. Undertakings

(a) The undersigned registrant hereby undertakes:

1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

ii. to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and

iii. to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

i. if the registrant is relying on Rule 430B: (A) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and (B) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

ii. if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is

asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

Explanation of Responses:

(c) The undersigned registrant hereby undertakes that:

1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Alpharetta, State of Georgia, on March 29, 2013.

SANUWAVE HEALTH, INC.

By:	/s/ Joseph Chiarelli
Name:	Joseph Chiarelli
Title:	Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Joseph Chiarelli and Barry J. Jenkins, and each of them, as his true and lawful attorneys-in-fact, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign any and all amendments (including post-effective amendments) to this registration statement and to sign a registration statement pursuant to Section 462(b) of the Securities Act of 1933, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signatures	Capacity	Date
By: /s/ Joseph Chiarelli Name: Joseph Chiarelli	Chief Executive Officer and Director (principal executive officer)	March 29, 2013
By: /s/ Barry J. Jenkins Name: Barry J. Jenkins	Chief Financial Officer and COO (principal financial and accounting officer)	March 29, 2013
By: /s/ Kevin A. Richardson, II Name: Kevin A. Richardson, II	Chairman of the Board of Directors	March 29, 2013
By: /s/ John F. Nemelka Name: John F. Nemelka	Director	March 29, 2013