SANUWAVE Health, Inc.
Form 10-Q
May 14, 2013
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2013

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

For the transition period from _____ to

Commission File Number 000-52985

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

Nevada	20-1176000
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11475 Great Oaks Way, Suite 150 Alpharetta, GA	30022
(Address of principal executive offices)	(Zip Code)

(770) 419-7525
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer ¨ Smaller reporting company x
(Do not check if a smaller reporting company)

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

As of May 9, 2013, there were issued and outstanding 21,726,536 shares of the registrant's common stock, $0.001 par value.

SANUWAVE Health, Inc.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of SANUWAVE Health, Inc. and its subsidiaries ("SANUWAVE" or the "Company") contains forward-looking statements. All statements in this Quarterly Report on Form 10-Q, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company's future financial results, clinical trial results, regulatory approvals, operating results, business strategies, projected costs, products, competitive positions, management's plans and objectives for future operations, and industry trends. These forward-looking statements are based on management's estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" and "co negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission, specifically the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 26, 2013 and in the Company's Quarterly Reports on Form 10-Q. Other risks and uncertainties are and will be disclosed in the Company's prior and future Securities and Exchange Commission (the "SEC") filings. These and many other factors could affect the Company's future financial condition and operating results and could cause actual results to differ materially from expectations based on forward-looking statements made in this document or elsewhere by the Company or on its behalf. The Company undertakes no obligation to revise or update any forward-looking statements. The following information should be read in conjunction with the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 26, 2013.

Except as otherwise indicated by the context, references in this Quarterly Report on Form 10-Q to "we," "us" and "our" are to the consolidated business of the Company.

PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2013	December 31, 2012
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 671,027	$ 70,325
Accounts receivable - trade, net of allowance for doubtful accounts of $50,100 in 2013 and $44,124 in 2012	93,461	87,826
Inventory (Note 4)	261,282	292,665
Prepaid expenses	116,406	128,495
TOTAL CURRENT ASSETS	1,142,176	579,311
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 5)	27,851	32,842
OTHER ASSETS	11,233	11,358
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 6)	1,150,336	1,227,025
TOTAL ASSETS	$ 2,331,596	$ 1,850,536
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$ 359,029	$ 555,898
Accrued expenses (Note 7)	623,311	721,916
Accrued employee compensation	376,175	534,659
Derivative liability (Note 8)	5,737,000	-
Senior secured convertible promissory notes (Note 8)	436,983	-
Subscription payable for senior secured convertible promissory notes (Note 8)	-	438,516
Interest payable, related parties (Note 9)	80,071	81,864
Capital lease payable, current portion (Note 13)	5,026	4,933
Liabilities related to discontinued operations	655,061	655,061
TOTAL CURRENT LIABILITIES	8,272,656	2,992,847
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 9)	5,372,743	5,372,743
Capital lease payable, non-current portion (Note 13)	2,659	3,951
TOTAL NON-CURRENT LIABILITIES	5,375,402	5,376,694
TOTAL LIABILITIES	13,648,058	8,369,541
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-

COMMON STOCK, par value $0.001, 150,000,000 shares authorized; 21,653,536 and 21,007,536 issued and outstanding in 2013 and 2012, respectively	21,654	21,008
ADDITIONAL PAID-IN CAPITAL	64,935,348	64,357,193
ACCUMULATED OTHER COMPREHENSIVE INCOME	6,191	13,116
ACCUMULATED DEFICIT	(76,279,655)	(70,910,322)
TOTAL STOCKHOLDERS' DEFICIT	(11,316,462)	(6,519,005)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 2,331,596	$ 1,850,536

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012
REVENUE	$ 201,234	$ 238,540
COST OF REVENUE	55,811	71,772
GROSS PROFIT	145,423	166,768
OPERATING EXPENSES		
Research and development	344,685	603,797
General and administrative	851,921	1,237,540
Depreciation	4,991	5,210
Amortization	76,689	76,689
TOTAL OPERATING EXPENSES	1,278,286	1,923,236
OPERATING LOSS	(1,132,863)	(1,756,468)
OTHER INCOME (EXPENSE)		
Loss on embedded conversion feature of Senior Secured Notes (Note 8)	(3,737,000)	-
Interest expense, net	(508,890)	(78,856)
Gain on sale of fixed assets	7,500	-
Gain on foreign currency exchange	1,920	9
TOTAL OTHER INCOME (EXPENSE)	(4,236,470)	(78,847)
LOSS BEFORE INCOME TAXES	(5,369,333)	(1,835,315)
INCOME TAX EXPENSE	-	-
NET LOSS	(5,369,333)	(1,835,315)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(6,925)	4,928
TOTAL COMPREHENSIVE LOSS	$ (5,376,258)	$ (1,830,387)
LOSS PER SHARE:		
Net loss - basic	$ (0.25)	$ (0.09)
Net loss - diluted	$ (0.25)	$ (0.09)
Weighted average shares outstanding - basic	21,278,128	20,907,536
Weighted average shares outstanding - diluted	21,278,128	20,907,536

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(5,369,333)	$(1,835,315)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization	76,689	76,689
Depreciation	4,991	5,210
Change in allowance for doubtful accounts	5,976	(2,520)
Stock-based compensation - employees, directors and advisors	317,601	262,176
Stock issued for consulting services	186,200	-
Loss on embedded conversion feature of Senior Secured Notes	3,737,000	-
Accrued interest on Senior Secured Notes	428,467	-
Gain on sale of property and equipment	(7,500)	-
Changes in assets - (increase)/decrease		
Accounts receivable - trade	(11,611)	(42,046)
Inventory	31,383	37,943
Prepaid expenses	12,089	(8,730)
Due from Pulse Veterinary Technologies, LLC	-	27,837
Other	125	(129)
Changes in liabilities - increase/(decrease)		
Accounts payable	(196,869)	(152,553)
Accrued employee compensation	(158,484)	158,559
Accrued expenses	(98,605)	(15,773)
Interest payable, related parties	(1,793)	(1,793)
NET CASH USED BY OPERATING ACTIVITIES	(1,043,674)	(1,490,445)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale of property and equipment	7,500	-
Purchase of property and equipment	-	(945)
NET CASH PROVIDED (USED) BY INVESTING ACTIVITIES	7,500	(945)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from subscriptions payable for senior secured convertible promissory notes	1,570,000	-
Proceeds from sale of capital stock - subscription agreement with related party	75,000	-
Payments of principal on capital lease	(1,199)	(1,112)
NET CASH PROVIDED (USED) BY FINANCING ACTIVITIES	1,643,801	(1,112)
EFFECT OF EXCHANGE RATES ON CASH	(6,925)	4,928
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	600,702	(1,487,574)

CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	70,325	3,909,383
CASH AND CASH EQUIVALENTS, END OF PERIOD	$671,027	$2,421,809
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$81,864	$81,864
Cash paid for capital lease interest	$160	$247

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

1. Nature of the Business

SANUWAVE Health, Inc. and subsidiaries (the "Company") is a shockwave technology company using noninvasive, high-energy, acoustic shockwaves 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 regenerative product in the United States is the demaPACE® device, which is in a supplemental Phase III clinical study for treating diabetic foot ulcers with possible FDA approval in 2015 subject to submission of satisfactory clinical study results.

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 is currently not marketing any commercial products in the United States. Revenue is from sales of the European Conformity Marking ("CE Mark") devices and accessories in Europe, Canada and Asia/Pacific.

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

2. Going concern

The continuation of the Company's business is dependent upon raising additional capital in the second quarter of 2013. As of March 31, 2013, the Company had cash and cash equivalents of $671,027 and negative working capital of $7,130,480. For the three months ended March 31, 2013 and 2012, the net cash used by operating activities was $1,043,674 and $1,490,445, respectively. The Company incurred a net loss of $5,369,333 for the three months ended March 31, 2013 and a net loss of $6,401,494 for the year ended December 31, 2012. Since inception, the Company has experienced recurring losses from operations and had an accumulated deficit of $76,279,655 at March 31, 2013. As a result, there is substantial doubt as to the Company's ability to continue as a going concern.

Management's plans are to obtain additional capital in the second quarter of 2013 through the issuance of common stock and/or other debt or equity securities and the Company has engaged financial advisors to assist with this process. The Company's cash and cash equivalents, at March 31, 2013, will support the Company's operations through May 2013. The Company expects to raise up to $600,000 through the issuance of unsecured promissory notes in May and June 2013 and/or amounts received on the Company's subscription agreement with an affiliated shareholder (see Note 13). In addition, the Company has filed a registration statement with the SEC to raise up to $6,000,000 through the sale of equity securities and has engaged a placement agent to lead this best efforts offering. Even if the Company is successful in each of the short term capital raising efforts described above, the Company may be required to raise additional funds by the end of 2013 to continue operations. Management expects the Company's monthly use of cash will be approximately $575,000 to $625,000 as the Company devotes substantial resources to the start of the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers by the end of the second quarter of 2013. The Company estimates the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

On March 8, 2013, the Company completed an offering in which it issued an aggregate of $2,000,000 of 18% senior secured convertible promissory notes (the “Senior Secured Notes”). The Senior Secured Notes are secured by the tangible and intangible assets of the Company. The Senior Secured Notes, as amended, will automatically convert to common stock if the Company raises $4,000,000 or more in gross proceeds through a qualified financing and/or license agreement as defined in the Senior Secured Note agreements, as amended. If the Company does not raise at least $4,000,000, the Senior Secured Notes will not automatically convert to common stock and will become due and payable. The Senior Secured Notes begin to mature in May 2013 and the Company is working with the holders to extend the maturity through the second quarter of 2013.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

2. Going concern (continued)

The Company may raise 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 (or some combination of the foregoing). 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 condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" in this Form 10-Q.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and footnotes required by United States generally accepted accounting principles for complete financial statements. The financial information as of March 31, 2013 and for the three months ended March 31, 2013 and 2012 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2013 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2013.

The condensed consolidated balance sheet at December 31, 2012 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements.

Significant Accounting Policies

For further information and a summary of significant accounting policies, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 26, 2013.

Fair Value Measurements

The carrying amounts reported in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable - trade, accounts payable and accrued expenses approximate fair value due to the short-term nature of these instruments.

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;

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

3. Summary of Significant Accounting Policies (continued)

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 following table sets forth a summary of changes in the fair value of the derivative liability for the three months ended March 31, 2013:

Description	Balance at December 31, 2012	New Issuances	Change in Fair Value	Balance at March 31, 2013
Derivative liability:				
Embedded conversion feature of Senior Secured Notes	$ -	$ 4,908,000	$ 829,000	$ 5,737,000

The Company accounts for derivative instruments under ASC 815, Accounting for Derivative Instruments and Hedging Activities, as amended and interpreted. ASC 815 requires that the Company recognize all derivatives on the balance sheet at fair value. On March 8, 2013, the Company completed an offering and issued Senior Secured Notes that contain an embedded conversion feature which is accounted for as a derivative liability. In recording this derivative liability, $2,000,000 was recorded as a debt discount and the remaining value along with the gains (losses) resulting from the changes in the fair value of the derivative instruments are recorded in the “loss on embedded conversion feature of Senior Secured Notes” in the accompanying condensed consolidated statements of comprehensive loss. The fair value of the embedded conversion feature is determined based on a lattice solution, binomial approach pricing model, and includes the use of unobservable inputs such as the expected term, anticipated volatility and risk-free interest rate.

The Company’s notes payable, related parties consist of $5,372,743 of principal at March 31, 2013 and December 31, 2012. Interest accrues on the notes at a rate of 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 $4,621,186 and $4,545,620 at March 31, 2013 and December 31, 2012, respectively.

Recently Issued Accounting Standards

New accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies. The Company does not expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company’s results of operations, financial position or cash flow.

In February 2013, the FASB issued Accounting Standards Update (“ASU”) No. 2013-02, which amends the guidance in Accounting Standard Codification (“ASC”) 220 on Comprehensive Income. Under the revised guidance, companies are

required to provide information about the amounts reclassified out of accumulated other comprehensive income ("AOCI") by component. In addition, companies are required to present, either on the face of the statement where net income (loss) is presented or in the notes, the effects on the line items of net income (loss) of significant amounts reclassified out of AOCI but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income (loss) in its entirety in the same reporting period. This amended guidance is to be applied prospectively and is effective for reporting periods (interim and annual) beginning after December 15, 2012 for public companies, with early adoption permitted. The Company adopted the revised guidance January 1, 2013, and reported significant items reclassified out of AOCI in the notes to the condensed consolidated financial statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

4. Inventory

Inventory consists of the following:

	March 31, 2013	December 31, 2012
Inventory - finished goods	$ 272,292	$ 306,706
Inventory - parts	76,090	83,509
Total	348,382	390,215
Allowance for losses and obsolescence	(87,100)	(97,550)
Net inventory	$ 261,282	$ 292,665

5. Property and equipment

Property and equipment consists of the following:

	March 31, 2013	December 31, 2012
Machines and equipment	$ 233,793	$ 233,793
Office and computer equipment	179,349	179,349
Software	41,872	41,872
Furniture and fixtures	25,679	25,679
Vehicles	-	22,531
Other assets	2,446	2,446
Total	483,139	505,670
Accumulated depreciation	(455,288)	(472,828)
Net property and equipment	$ 27,851	$ 32,842

The aggregate depreciation related to property and equipment charged to operations was $4,991 and $5,210 for the three months ended March 31, 2013 and 2012, respectively.

6. Intangible assets

Intangible assets consist of the following:

	March 31, 2013	December 31, 2012
Patents, at cost	$ 3,502,135	$ 3,502,135
Less accumulated amortization	(2,351,799)	(2,275,110)
Net intangible assets	$ 1,150,336	$ 1,227,025

The aggregate amortization charged to operations was $76,689 and $76,689 for the three months ended March 31, 2013 and 2012, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

7. Accrued expenses

Accrued expenses consist of the following:

	March 31, 2013	December 31, 2012
Accrued executive severance	$ 441,020	$ 542,269
Accrued audit and tax preparation	51,900	$ 102,600
Accrued legal professional fees	47,938	23,519
Accrued other	82,453	53,528
	$ 623,311	$ 721,916

8. 18% Senior secured convertible promissory notes

During the period from November 2012 through March 8, 2013, the Company entered subscriptions payable for 18% senior secured convertible promissory notes (as previously defined as the “Senior Secured Notes”) from select accredited investors. The Company completed the offering and issued an aggregate $2,000,000 in Senior Secured Notes on March 8, 2013. As of March 31, 2013, the Company had outstanding $2,000,000 in Senior Secured Notes and had $66,520 in accrued interest expense. 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. Kevin A. Richardson, II, chairman of the board of directors of the Company, purchased $60,000 of the Senior Secured Notes.

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 a conversion price of $0.20 per share. Upon the consummation of a qualified financing and/or technology license, as defined in the Senior Secured Note agreements, as amended, of $4,000,000 or more by the Company, the principal and interest on the Senior Secured Notes will automatically 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 securities 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 conversion feature embedded in the Senior Secured Notes is accounted for as a derivative liability, and resulted in the creation at issuance of a discount to the carrying amount of the debt in the amount of $2,000,000, which is being amortized as additional interest expense using the straight-line method over the term of the Senior Secured Notes (the Company determined that using the straight-line method of amortization did not yield a materially different amortization schedule than the effective interest method). The embedded conversion feature is recorded at fair value and is marked to market at each period, with the resulting change in fair value being recorded in the “loss on embedded conversion feature of Senior Secured Notes” in the accompanying condensed consolidated statements of comprehensive loss. The derivative liability for the embedded conversion feature of the Senior Secured Notes, at fair value, was $5,737,000 at March 31, 2013.

Accrued interest expense on the Senior Secured Notes, including amortization of the debt discount, totaled $428,467 for the three months ended March 31, 2013.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

9. Notes payable, related parties

The notes payable, related parties consist of the following:

	March 31, 2013	December 31, 2012
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 $80,071 and $81,864 at March 31, 2013 and December 31, 2012, respectively.

Interest expense on notes payable to related parties totaled $80,071for the three months ended March 31, 2013 and 2012, respectively.

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.

At March 31, 2013, the Company had federal net operating loss ("NOL") carryforwards of $54,017,215 for tax years through the year ended December 31, 2012, that will begin to expire in 2025. The use of deferred tax assets, including federal net operating losses, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, Income Taxes (formerly SFAS No. 109), the Company's management believes that there is not sufficient evidence at March 31, 2013 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2013. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including NOL carryforwards.

The Company's ability to use its NOL 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 NOL carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which NOL 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 NOL carryforwards for federal income tax purposes.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2013

11. Equity transactions

2013 Additional Capital Raise and Consulting Agreements

The continuation of the Company's business is dependent upon raising additional capital. 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. On February 25, 2013, the Company issued to a consultant 2,000,000 warrants to purchase the Company's common stock at $0.35 per share. The five 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 on or prior to June 1, 2013 (see Note 12).

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. The fair value of the common stock of $35,000, based upon the closing market price of the Company's common stock at the date the common stock was issued, was recorded as consulting expense for the three months ended March 31, 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 (see Note 12). 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 issued 246,000 shares of common stock under these agreements through March 31, 2013. The fair value of the common stock of $151,200, which was based upon the closing market price of the Company's common stock at the dates the common stock was issued, was recorded as consulting expense for the three months ended March 31, 2013.

12. Warrants

A summary of the warrant activity as of March 31, 2013 and December 31, 2012, and the changes during the three months ended March 31, 2013, is presented as follows:

	Class A Warrants	Class B Warrants	Class D Warrants	Class E Warrants	Class F Warrants
Outstanding as of December 31, 2012	1,106,627	1,106,627	1,950,167	3,576,737	-
Issued	-	-	-	-	2,000,000
Exercised	-	-	-	-	-
Expired	-	-	(1,950,167)	-	-
Outstanding as of March 31, 2013	1,106,627	1,106,627	-	3,576,737	2,000,000

The Class A, Class B, Class E and Class F Warrants expire five years from date of issuance and the Class D Warrants expired two years from date of issuance. 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 F Warrants have an exercise price of $0.35 per share. The Class D Warrants expired unexercised on January 31, 2013.

As discussed in Note 11 above, on February 25, 2013, the Company issued to a consultant 2,000,000 warrants to purchase the Company's common stock at $0.35 per share. The five 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 on or prior to June 1, 2013. The Company will record the underlying cost of the warrants as a cost of capital upon completion of a qualified offering, if it occurs.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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12. Warrants (continued)

As discussed in Note 11 above, 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 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. The Company will record the underlying cost of the warrants as a cost of capital upon completion of a qualified offering, if it occurs.

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 company.

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.

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 March 31, 2013, the Subscriber had paid the Company $100,000 and was issued 400,000 shares of unregistered common stock of the Company. The Company will record the additional $900,000 and issue the corresponding 3,600,000 shares of common stock in the periods in which the Purchase Price is received.

Operating Leases

The Company leases office and warehouse space. Rent expense for the three months ended March 31, 2013 and 2012, was $27,474 and $86,798, respectively.

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 March 31, 2013 and December 31, 2012 totaled $7,681 and $6,468, respectively. The net book value of such equipment at March 31, 2013 and December 31, 2012 totaled $6,872 and $8,085, respectively.

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 and the appeal was heard by a three judge panel on April 29, 2013. HealthTronics, Inc. has been responsible for the defense of the lawsuit on behalf of the Company and believes the case is unfounded and is contesting the claims vigorously.

14. 401(k) plan

The Company sponsors a 401(k) plan that covers all employees who meet the eligibility requirements. The Company amended the 401(k) plan to make the Company matching contribution discretionary and discontinued the Company match effective February 1, 2012. The Company contributed $0 and $9,664 to the plan for the three months ended March 31, 2013 and 2012, 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. On February 21, 2013, the Stock Incentive Plan was amended to reserve a total of 8,500,000 shares of common stock for grant.

On February 21, 2013, the Company, by mutual agreement with all 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. Using the Black-Scholes option pricing model, management has determined that the options at the grant date, net of the value of the cancelled options as of the date of cancellation, had an average fair value per

share of $0.223 resulting in total compensation of $499,621. Compensation cost will be recognized over the requisite service period.

On February 21, 2013, 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 $0.35 per share in place of an annual cash consulting fee. Using the Black-Scholes option pricing model, management has determined that the options at the grant date had a fair value per share of $0.25 resulting in total compensation of $25,000. Compensation cost will be recognized over the calendar year 2013.

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15. Stock-based compensation (continued)

On February 25, 2013, Joseph Chiarelli joined the Company to serve as the Chief Executive Officer and a director of the Company. 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. Using the Black-Scholes option pricing model, management has determined that the options had an average fair value per share of $0.207 resulting in total compensation of $465,000. Compensation cost will be recognized over the requisite service 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.

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 three months ended March 31, 2013 and 2012:

	2013		2012	
Weighted average expected life in years	4.3		5.2	
Weighted average risk free interest rate	0.72	%	0.95	%
Weighted average volatility	150.0	%	75.0	%
Forfeiture rate	0.0	%	0.0	%
Expected dividend yield	0.0	%	0.0	%

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. 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. Since there is a limited trading history for the Company's common stock, the expected volatility is based on a combination of historical data from companies similar in size, value and trading history for the Company's common stock. 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. Management estimates pre-vesting forfeitures at the time of grant and revises 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 dividend yield is based on historical dividend experience, however, since inception the Company has not declared dividends.

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, $317,601 and $262,176 for the three months ended March 31, 2013 and 2012, respectively.

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

A summary of option activity as of March 31, 2013 and December 31, 2012, and the changes during the three months ended March 31, 2013, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2012	5,229,330	$ 2.25
Granted	4,593,644	$ 0.35
Exercised	-	$ -
Cancelled	(1,113,644)	$ 2.92
Forfeited or expired	(105,000)	$ 2.93
Outstanding as of March 31, 2013	8,604,330	$ 1.14
Exercisable	4,733,572	$ 1.80

The weighted average remaining contractual term for outstanding and exercisable stock options was 7.5 years as of March 31, 2013, and 6.6 years as of December 31, 2012.

A summary of the Company's nonvested options as of March 31, 2013 and December 31, 2012, and changes during the three months ended March 31, 2013, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2012	508,750	$ 0.66
Granted	4,593,644	$ 0.35
Vested	(1,180,386)	$ 0.41
Cancelled	(43,750)	$ 2.87
Forfeited or expired	(7,500)	$ 5.25
Outstanding as of March 31, 2013	3,870,758	$ 0.33

16. Changes in other comprehensive loss

The amounts recognized in other comprehensive loss for the three months ended March 31, 2013 were as follows:

	Currency Translations	Total
Balance, at December 31, 2012	$ 13,116	$ 13,116
Other comprehensive loss before reclassifications	(6,925)	(6,925)
Amounts reclassified from AOCI	-	-

Net change in other comprehensive loss		(6,925)		(6,925)
Balance, at March 31, 2013	$	6,191	$	6,191

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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17. Earnings (loss) per share

The Company calculates net income (loss) per share in accordance with ASC 260, Earnings Per Share (formerly SFAS No. 128, Earnings Per Share). Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. To the extent that securities are “anti-dilutive,” they are excluded from the calculation of diluted net income (loss) per share.

As a result of the net loss for the three months ended March 31, 2013 and 2012, 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 26,726,924 shares and 14,436,697 shares at March 31, 2013 and 2012, respectively.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this report, and together with our audited consolidated financial statements, related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as of and for the year ended December 31, 2012 included in our Annual Report on Form 10-K filed with the SEC on March 26, 2013.

Overview

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

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

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

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

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

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

Recent Developments

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct 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 identified and entered into contracts with clinical study sites for participation in the clinical trial. We expect that patient enrollment will begin in the second quarter of 2013.

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

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

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

Importantly, the study design allows for controlled interim monitoring of the data by an independent Data Monitoring Committee (DMC) to determine whether study success has been achieved. We anticipate that the first analysis of the success of the study will occur after 90 patients (approximately 45 per arm) have completed the 12-week primary efficacy evaluation period. If study data achieves pre-defined statistical and clinical success criteria associated with wound closure favoring dermaPACE, then the clinical trial can be stopped, and we will submit 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.

Previous clinical work supporting our current dermaPACE clinical study

The dermaPACE device completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA Application was filed with the FDA in June 2011. The primary study goal was to

establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

A summary of the key study findings were as follows:

- Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intent-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 procedure, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control ($p<0.05$).

- Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20.0% in the sham-control group.

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

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

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's failure to meet the study's primary endpoint of 100% wound closure compared with sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency was for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We evaluated

the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we decided to conduct supplemental clinical work as discussed above.

Financial Overview

Since our inception in 2005, we have funded our operations from the sale of capital stock, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009, and product sales. At March 31, 2013, our balance of cash and cash equivalents totaled $671,027 and we had a net working capital deficit of $7,130,480. We will require additional capital in the second quarter of 2013 to continue as a going concern. There can be no assurance that we will be successful in raising such capital.

Management's plans are to obtain additional capital in the second quarter of 2013 through the issuance of common stock and/or other debt or equity securities and we have engaged financial advisors to assist with this process. Our cash and cash equivalents, at March 31, 2013, will support our operations through May 2013. We expect to raise up to $600,000 through the issuance of unsecured promissory notes in May and June 2013 and/or amounts received on the our Subscription Agreement with an affiliated shareholder. In addition, we have filed a registration statement with the SEC to raise up to $6,000,000 through the sale of equity securities and have engaged a placement agent to lead this best efforts offering. We expect our monthly use of cash will be approximately $575,000 to $625,000 as we devote substantial resources to the start of the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers by the end of the second quarter of 2013. Management estimates the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

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

Since our inception, we have incurred losses from operations each year. As of March 31, 2013, we had an accumulated deficit of $76,279,655. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next several years as we continue to fund the dermaPACE clinical trial and the FDA approval process.

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

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of successful marketing, sales and distribution;
- the cost and timing associated with establishing reimbursement for our products;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior.

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth under the section entitled "Risk Factors – Risks Related to Our Business" in our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 26, 2013.

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 embedded conversion feature of

the Senior Secured Notes and the estimated fair value assigned to the common stock and warrants issued for consulting agreements. 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 filed with our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 26, 2013, 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

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. 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

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.

Results of Operations for the Three Months ended March 31, 2013 and 2012 (Unaudited)

Revenue and Cost of Revenue

Revenue for the three months ended March 31, 2013 was $201,234, compared to $238,540 for the same period in 2012, a decrease of $37,306, or 16%. The decrease in revenues for 2013 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 2013 as a result of more devices in use.

Cost of revenue for the three months ended March 31, 2013 was $55,811, compared to $71,772 for the same period in 2012. Gross profit as a percentage of revenue was 72% for the three months ended March 31, 2013, as compared to 70% for the same period in 2012. The slight increase in gross profit as a percentage of revenue in 2013 was due to increased sales of higher margin applicators in 2013, as compared to 2012.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2013 were $344,685, compared to $603,797 for the same period in 2012, a decrease of $259,112, or 43%. Research and development expenses decreased in 2013 due to reduced headcount as compared to the same period in 2012 and less consulting services in 2013 related to clinical results analysis than incurred in 2012 on the dermaPACE phase III clinical trial.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2013 were $851,921, compared to $1,237,540 for the same period in 2012, a decrease of $385,619, or 31%. The decrease in general and administrative

expenses is primarily due to a reduction in headcount, the consolidation of our operations into one office effective November 2012 and reduction of legal expenses related to patents offset by additional consulting expenses incurred in 2013 for financial advisors and investor relations.

Other Income (Expense)

Other income (expense) was a net expense of $4,236,470 for the three months ended March 31, 2013 as compared to a net expense of $78,847 for the same period in 2012, an increase of $4,157,623. The increase was due to the issuance of Senior Secured Notes on March 8, 2013 and the resultant recording of $3,737,000 in non-cash loss on the embedded conversion feature of the Senior Secured Notes and the accrued interest expense, including amortization of debt discount, on the Senior Secured Notes of $428,467.

Provision for Income Taxes

At March 31, 2013, we had federal net operating loss carryforwards of $54,017,215 for tax years through the year ended December 31, 2012 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes. We have recorded a full valuation allowance as of March 31, 2013, due to uncertainties related to our ability to utilize our deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire.

Net Loss

Net loss for the three months ended March 31, 2013 was $5,369,333, or ($0.25) per basic and diluted share, compared to a net loss of $1,835,315, or ($0.09) per basic and diluted share, for the same period in 2012, an increase in the net loss of $3,534,018, or 193%. The increase in the net loss was due to the issuance of the Senior Secured Notes, which was completed on March 8, 2013, and the resultant recording of $3,737,000 in non-cash loss on the embedded conversion feature of the Senior Secured Notes and the accrued interest expense, including amortization of debt discount, on the Senior Secured Notes of $428,467.

We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device clinical trial for the treatment of diabetic foot ulcers.

Liquidity and Capital Resources

The continuation of our business is dependent upon raising additional capital in the second quarter of 2013. Management's plans are to obtain additional capital in the second quarter of 2013 through the issuance of common stock and/or other debt or equity securities and we have engaged financial advisors to assist with this process. Our cash and cash equivalents, at March 31, 2013, will support our operations through May 2013. We expect to raise up to $600,000 through the issuance of unsecured promissory notes in May and June 2013 and/or amounts received on the our Subscription Agreement with an affiliated shareholder. In addition, we have filed a registration statement with the SEC to raise up to $6,000,000 through the sale of equity securities and have engaged a placement agent to lead this best efforts offering. Even if we are successful in each of the short term capital raising efforts described above, we may be required to raise additional funds by the end of 2013 to continue operations. We expect our monthly use of cash will be approximately $575,000 to $625,000 as we devote substantial resources to the start of the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers by the end of the second quarter of 2013. Management estimates the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

On March 8, 2013, we completed a private placement with select accredited investors of an aggregate $2,000,000 of Senior Secured Notes. The Senior Secured Notes, as amended, 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. Based on our current financial condition, we may be unable to obtain the additional financing that we are seeking 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. The Senior Secured Notes are secured by the tangible and intangible assets of the Company. The Senior Secured Notes begin to mature in May 2013 and we are working with the holders to extend the maturity through the second quarter of 2013.

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 $5,369,333 and $1,835,315 for the three months ended March 31, 2013 and 2012, respectively. These operating losses create uncertainty about our ability to continue as a going concern. For the three months ended March 31, 2013 and 2012, the net cash used by operating activities by us was $1,043,674 and $1,490,445, respectively. As of March 31, 2013, we had cash and cash equivalents of $671,027. We may raise 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 (or some combination of the foregoing). 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.

For the three months ended March 31, 2013 and 2012, net cash used by operating activities was $1,043,674 and $1,490,445, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for 2013, as compared to the same period for 2012, of $446,771, or 30%, was primarily due to reductions in headcount, operating expenses and clinical expenses in 2013 as compared to the same period in 2012. Net cash provided (used) by financing activities for the three months ended March 31, 2013 and 2012 was $1,643,801 and ($1,112), respectively, which in 2013 consisted of the proceeds from the subscriptions payable for Senior Secured Notes of $1,570,000 and the proceeds from the Subscription Agreement of $75,000. Cash and cash equivalents increased by $600,702 for the three months ended March 31, 2013. Cash and cash equivalents decreased by $1,487,574 for the three months ended March 31, 2012.

Segment and Geographic 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. Our revenue is generated from sales in Europe, Canada and Asia/Pacific. We are currently not marketing any commercial products in the United States.

Contractual Obligations

Our major outstanding contractual obligations relate to our operating leases for our facilities, purchase and supplier obligations for product component materials and equipment, and our notes payable. We have disclosed these obligations in our most recent Annual Report on Form 10-K.

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 condensed consolidated financial condition and results of operations.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act are accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2013. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2013.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 6. EXHIBITS

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 18% Senior Secured Convertible Promissory Note of SANUWAVE Health, Inc. (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).
10.1	Employment Agreement, dated as of February 21, 2013, by and between SANUWAVE Health, Inc. and Joseph Chiarelli (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Principal Executive Officer.
32.2*	Section 1350 Certification of the Chief Financial Officer.
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

** 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

Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

SIGNATURES

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

Dated: May 14, 2013

SANUWAVE HEALTH, INC.

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

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

Signatures	Capacity	Date
By: /s/ Joseph Chiarelli Name: Joseph Chiarelli	Chief Executive Officer and Director (principal executive officer)	May 14, 2013
By: /s/ Barry J. Jenkins Name: Barry J. Jenkins	Chief Financial Officer (principal financial and accounting officer)	May 14, 2013
By: /s/Kevin A. Richardson, II Name: Kevin A. Richardson, II	Chairman of the Board of Directors	May 14, 2013
By: /s/ John F. Nemelka Name: John F. Nemelka	Director	May 14, 2013