

SANUWAVE Health, Inc.
Form 10-Q
November 14, 2012

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

☐ 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
(State or other jurisdiction of
incorporation or organization)

20-1176000
(I.R.S. Employer
Identification No.)

11475 Great Oaks Way, Suite 150
Alpharetta, GA
(Address of principal executive offices)

30022
(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. ☒ 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). ☒ 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):

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Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(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 ☒ No

As of November 9, 2012, there were issued and outstanding 20,907,536 shares of the registrant's common stock, \$.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, 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 “continue,” the negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in 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, 2011, filed on March 14, 2012 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 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, 2011, filed on March 14, 2012.

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

	September 30, 2012 (Unaudited)	December 31, 2011 (Unaudited)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 361,263	\$ 3,909,383
Accounts receivable - trade, net of allowance for doubtful accounts of \$47,313 in 2012 and \$74,852 in 2011	78,287	81,565
Inventory (Note 6)	294,898	396,284
Prepaid expenses	203,132	162,975
Due from Pulse Veterinary Technologies, LLC	-	27,837
TOTAL CURRENT ASSETS	937,580	4,578,044
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 7)	37,904	51,206
OTHER ASSETS	3,191	3,192
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 8)	1,303,715	1,533,782
TOTAL ASSETS	\$ 2,282,390	\$ 6,166,224
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	\$ 402,358	\$ 756,657
Accrued employee compensation	1,107,083	632,333
Accrued expenses (Note 10)	173,588	190,583
Interest payable, related parties (Note 12)	81,864	81,864
Capital lease payable, current portion (Note 14)	4,841	4,576
Liabilities related to discontinued operations	655,061	655,061
TOTAL CURRENT LIABILITIES	2,424,795	2,321,074
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 12)	5,372,743	5,372,743
Capital lease payable, non-current portion (Note 14)	5,220	8,884
TOTAL NON-CURRENT LIABILITIES	5,377,963	5,381,627
TOTAL LIABILITIES	7,802,758	7,702,701
COMMITMENTS AND CONTINGENCIES (Note 14)	-	-
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value \$0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-

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COMMON STOCK, par value \$0.001, 150,000,000 shares and 50,000,000 shares authorized in 2012 and 2011, respectively; 20,907,536 issued and outstanding in 2012 and 2011 (Note 4)	20,908	20,908
ADDITIONAL PAID-IN CAPITAL	63,660,709	62,940,977
ACCUMULATED OTHER COMPREHENSIVE INCOME	14,055	10,466
RETAINED DEFICIT	(69,216,040)	(64,508,828)
TOTAL STOCKHOLDERS' DEFICIT	(5,520,368)	(1,536,477)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$2,282,390	\$6,166,224

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
REVENUES	\$ 178,256	\$ 161,678	\$ 627,153	\$ 577,180
COST OF REVENUES	43,965	48,475	197,898	189,006
GROSS PROFIT	134,291	113,203	429,255	388,174
OPERATING EXPENSES				
Research and development	440,193	623,318	1,391,634	2,167,735
General and administrative	977,859	1,493,963	3,252,127	4,386,538
Depreciation	4,973	971	15,313	13,452
Amortization	76,689	76,689	230,067	230,067
TOTAL OPERATING EXPENSES	1,499,714	2,194,941	4,889,141	6,797,792
OPERATING LOSS	(1,365,423)	(2,081,738)	(4,459,886)	(6,409,618)
OTHER INCOME (EXPENSE)				
Extinguishment of debt	-	-	-	(1,318,781)
Interest expense, net	(81,894)	(76,578)	(241,196)	(392,652)
Gain (loss) on foreign currency exchange	46	(25,723)	(6,130)	(43,521)
Transitional services provided to Pulse Veterinary Technologies, LLC	-	112,500	-	337,500
TOTAL OTHER INCOME (EXPENSE)	(81,848)	10,199	(247,326)	(1,417,454)
LOSS BEFORE INCOME TAXES	(1,447,271)	(2,071,539)	(4,707,212)	(7,827,072)
INCOME TAX EXPENSE	-	-	-	-
NET LOSS	(1,447,271)	(2,071,539)	(4,707,212)	(7,827,072)
OTHER COMPREHENSIVE INCOME				
Foreign currency translation adjustments	4,623	17,128	3,589	30,416
TOTAL COMPREHENSIVE LOSS	\$(1,442,648)	\$(2,054,411)	\$(4,703,623)	\$(7,796,656)
LOSS PER SHARE:				
Net loss - basic	\$(0.07)	\$(0.10)	\$(0.23)	\$(0.41)
Net loss - diluted	\$(0.07)	\$(0.10)	\$(0.23)	\$(0.41)
Weighted average shares outstanding - basic	20,907,536	20,907,536	20,907,536	19,196,236
Weighted average shares outstanding - diluted	20,907,536	20,907,536	20,907,536	19,196,236

See accompanying notes to unaudited condensed
consolidated financial statements.

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

	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(4,707,212)	\$(7,827,072)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization	230,067	230,067
Depreciation	15,313	13,452
Change in allowance for doubtful accounts	(27,539)	25,726
Stock-based compensation	719,732	550,387
Accrued interest	-	166,618
Extinguishment of debt	-	1,318,781
Changes in assets - (increase)/decrease		
Accounts receivable - trade	30,817	(19,443)
Inventory	101,386	37,980
Prepaid expenses	(40,157)	(32,740)
Due from Pulse Veterinary Technologies, LLC	27,837	(84,650)
Other	1	(133)
Changes in liabilities - increase/(decrease)		
Accounts payable	(354,299)	(668,431)
Accrued employee compensation	474,750	(628,772)
Accrued expenses	(16,995)	(74,836)
Interest payable, related parties	-	(1,113)
NET CASH USED BY OPERATING ACTIVITIES	(3,546,299)	(6,994,179)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(2,011)	(36,667)
NET CASH USED BY INVESTING ACTIVITIES	(2,011)	(36,667)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from private placement	-	8,467,121
Proceeds from unit options exercised, related parties	-	2,463,008
Proceeds from unit options exercised	-	1,437,326
Payment of principal on capital lease	(3,399)	-
NET CASH PROVIDED (USED) BY FINANCING ACTIVITIES	(3,399)	12,367,455
EFFECT OF EXCHANGE RATES ON CASH	3,589	30,416
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,548,120)	5,367,025
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,909,383	417,457
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$361,263	\$5,784,482

SUPPLEMENTAL INFORMATION

Cash paid for interest, related parties	\$242,903	\$242,903
Cash paid for capital lease interest	\$676	\$-
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Capital stock issued in exchange for notes payable, related parties	\$-	\$4,413,908

See accompanying notes to unaudited condensed consolidated financial statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012

1. Nature of the Business

SANUWAVE Health, Inc. and subsidiaries (the “Company”) is an emerging global regenerative medicine company focused on the development and commercialization of noninvasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. The Company’s portfolio of products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions. The Company currently does not have 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.

2. Basis of Presentation and Principles of Consolidation

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 September 30, 2012 and for the three and nine months ended September 30, 2012 and 2011 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 and nine month periods ended September 30, 2012 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2012.

The condensed consolidated balance sheet at December 31, 2011 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.

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, 2011, filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2012. Please also refer to Note 5 to the condensed consolidated financial statements in this Form 10-Q regarding the Company’s adoption of recent accounting pronouncements.

3. Going concern

The Company incurred a net loss of \$4,707,212 for the nine months ended September 30, 2012 and a net loss of \$10,238,797 for the year ended December 31, 2011. The Company had cash and cash equivalents of \$361,263 at September 30, 2012. These operating losses 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. Management’s plans are to obtain additional capital which may include: raising additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt; an investment by a strategic partner in a specific clinical indication or market opportunity; or selling all or a portion of the Company’s 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 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 report.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012

4. 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, \$0.001 par value per share (the “Common Stock”), at a purchase price of \$3.25 per share, for gross proceeds of \$9,114,927. The net proceeds received by the Company were \$8,467,121, net of offering costs of \$647,806. As part of the private placement, the investors were issued five-year warrants to purchase up to 2,804,593 shares of 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 of the 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.

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 offerings and promissory notes

During the year ended December 31, 2010, the Company issued ten promissory notes totaling \$2,450,000. On October 12, 2010, in conjunction with an offering of securities (the “Offering”) of the Company pursuant to an exemption from registration under the Securities Act, the Company 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 (as described below) equal to (i) the unpaid principal and interest on each such note, divided by (ii) 2. Each “Unit” in the Offering 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. The unpaid principal and interest on the notes totaled \$2,517,660,

and this sum was exchanged into a total of 1,258,830 Units which consisted of 1,258,830 shares of Common Stock, 1,258,830 Class D Warrants and 1,258,830 Options.

The chairman of the board of directors of the Company exchanged promissory notes totaling \$1,790,504 and the brother of a member of the board of directors of the Company exchanged promissory notes totaling \$522,504 in the Offering.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012

4. Equity transactions (continued)

On September 30, 2010, in conjunction with an offering of securities of the Company pursuant to an exemption from registration under the Securities Act, the Company issued 150,000 Units to certain accredited investors 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 of the Company exempt from registration under the Securities Act, the Company issued 250,000, 142,500 and 382,500 Units to 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, the Company sold 925,000 Units, which consisted of 925,000 shares of Common Stock, 925,000 Class D Warrants and 925,000 Options. This included 175,000 Units purchased by the brother of a member of the board of directors of the Company 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 to the Company. In connection with the exercise of the Options, the Company issued 101,163 shares of Common Stock and 101,163 Class D Warrants. 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.

5. Recently Issued Accounting Standards

There have been no recently issued accounting standards that have an impact on our condensed consolidated financial statements.

6. Inventory

Inventory consists of the following:

	September 30, 2012	December 31, 2011
Inventory - finished goods	\$ 306,778	\$ 412,291
Inventory - parts	86,420	113,593
Total	393,198	525,884
Provision for losses and obsolescence	(98,300)	(129,600)
Net inventory	\$ 294,898	\$ 396,284

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012

7. Property and equipment

Property and equipment consists of the following:

	September 30, 2012	December 31, 2011
Machines and equipment	\$ 233,793	\$ 232,848
Office and computer equipment	224,600	224,600
Leasehold improvements	67,421	67,421
Furniture and fixtures	25,679	24,613
Vehicles	22,531	22,531
Software	41,872	41,872
Other assets	2,378	2,378
Total	618,274	616,263
Accumulated depreciation	(580,370)	(565,057)
Net property and equipment	\$ 37,904	\$ 51,206

The aggregate depreciation related to property and equipment charged to operations was \$4,973 and \$971 for the three months ended September 30, 2012 and 2011, respectively, and \$15,313 and \$13,452 for the nine months ended September 30, 2012 and 2011, respectively.

8. Intangible assets

Intangible assets consist of the following:

	September 30, 2012	December 31, 2011
Patents, at cost	\$ 3,502,135	\$ 3,502,135
Less accumulated amortization	(2,198,420)	(1,968,353)
Net intangible assets	\$ 1,303,715	\$ 1,533,782

The aggregate amortization charged to operations was \$76,689 and \$76,689 for the three months ended September 30, 2012 and 2011, respectively, and \$230,067 and \$230,067 for the nine months ended September 30, 2012 and 2011, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012

9. 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;

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 September 30, 2012 and December 31, 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 \$4,471,070 and \$4,253,362 at September 30, 2012 and December 31, 2011, respectively.

10. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2012	December 31, 2011
Accrued legal professional fees	\$ 54,130	\$ 61,000
Accrued audit and tax preparation	83,532	75,516
Accrued other	35,926	54,067
	\$ 173,588	\$ 190,583

11. 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012

11. Income taxes (continued)

At September 30, 2012, the Company had federal net operating loss ("NOL") carryforwards of \$49,172,791 for tax years through the year ended December 31, 2011, 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 September 30, 2012 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2012. 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.

12. Notes payable, related parties

The notes payable consist of the following:

	September 30, 2012	December 31, 2011
Notes payable, unsecured, bearing interest at 6% to HealthTronics, Inc., a shareholder of the Company. The notes were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. 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 September 30, 2012 and December 31, 2011. Accrued interest not payable until August 1, 2015 totaled \$1,372,743 at September 30, 2012 and December 31, 2011.	\$ 5,372,743	\$ 5,372,743
Less current portion	-	-

Non-current portion	\$ 5,372,743	\$ 5,372,743
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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.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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12. Notes payable, related parties (continued)

Interest expense on notes payable to related parties totaled \$81,864 and \$81,864 for the three months ended September 30, 2012 and 2011, respectively, and \$242,903 and \$408,408 for the nine months ended September 30, 2012 and 2011, respectively.

13. 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 and nine months ended September 30, 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 14,189,481 shares and 13,067,947 shares at September 30, 2012 and 2011, respectively.

14. Commitments and contingencies

Operating Leases

The Company leases office and warehouse space. Rent expense for the three months ended September 30, 2012 and 2011, was \$68,462 and \$87,312, respectively, and \$238,712 and \$262,194 for the nine months ended September 30, 2012 and 2011, 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 September 30, 2012 and December 31, 2011 totaled \$5,255 and \$1,617, respectively. The net book value of such equipment at September 30, 2012 and December 31, 2011 totaled \$9,297 and \$12,935, respectively.

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, 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.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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15. 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 their compensation 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 \$0 and \$19,535 to the plan for the three months ended September 30, 2012 and 2011, respectively, and \$9,664 and \$55,937 for the nine months ended September 30, 2012 and 2011, respectively.

16. 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 "Amended Plan"). The Amended 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. The Amended Plan is currently administered by the board of directors of the Company. The Amended Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. Stock options granted under the Amended 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. The Amended Plan reserves 5,000,000 shares of Common Stock for grant.

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 amortized to expense over the options' vesting periods for the year ended December 31, 2011: risk-free interest rate of 1.32%, expected dividend yield of 0%, volatility factor of the expected market price of the Company's Common Stock of 65%, forfeiture rate of 0% and weighted average expected life of the option of 5.76 years. Since there is a limited trading history for the Company's Common Stock, the expected volatility is based on historical data from companies similar in size and value to the Company. The expected dividend yield is based on the Company's historical dividend experience, however, since inception, the Company has 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. The Company 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 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 Company recognized as compensation cost for all outstanding stock options, restricted stock and warrants granted to employees, directors and advisors, \$217,686 and \$250,177 for the three months ended September 30, 2012 and 2011, respectively, and \$719,732 and \$550,387 for the nine months ended September 30, 2012 and 2011, respectively.

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

A summary of option activity as of September 30, 2012 and December 31, 2011, and the changes during the three and nine months ended September 30, 2012, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2011	4,365,546	\$ 2.82
Granted	100,000	\$ 0.44
Exercised	-	\$ -
Forfeited or expired	(54,000)	\$ 2.73
Outstanding as of March 31, 2012	4,411,546	\$ 2.77
Granted	-	\$ -
Exercised	-	\$ -
Forfeited or expired	(97,216)	\$ 2.91
Outstanding as of June 30, 2012	4,314,330	\$ 2.76
Granted	-	\$ -
Exercised	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of September 30, 2012	4,314,330	\$ 2.76
Exercisable	3,424,330	\$ 2.95

The weighted average remaining contractual term for outstanding and exercisable stock options was 5.8 years as of September 30, 2012, and 6.3 years as of December 31, 2011.

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

A summary of the Company's nonvested options as of September 30, 2012 and December 31, 2011, and changes during the three and nine months ended September 30, 2012, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2011	1,314,722	\$ 2.49
Granted	100,000	\$ 0.44
Vested	(51,250)	\$ 2.29
Forfeited or expired	(16,500)	\$ 3.19
Outstanding as of March 31, 2012	1,346,972	\$ 2.33
Granted	-	\$ -
Vested	(121,722)	\$ 5.25
Forfeited or expired	(1,500)	\$ 3.71
Outstanding as of June 30, 2012	1,223,750	\$ 2.04
Granted	-	\$ -
Vested	(333,750)	\$ 2.00
Forfeited or expired	-	\$ -
Outstanding as of September 30, 2012	890,000	\$ 2.05

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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17. Warrants

The Company grants warrants in connection with equity share purchases by investors as an additional incentive for providing long term equity capital to the Company. The warrants are granted at negotiated prices in connection with the equity share purchases. A summary of the warrant activity as of September 30, 2012 and December 31, 2011, and the changes during the three and nine months ended September 30, 2012, is presented as follows:

	Class A Warrants	Class B Warrants	Class D Warrants	Class E Warrants
Outstanding as of December 31, 2011	1,106,627	1,106,627	4,235,160	3,576,737
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Outstanding as of March 31, 2012	1,106,627	1,106,627	4,235,160	3,576,737
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Outstanding as of June 30, 2012	1,106,627	1,106,627	4,235,160	3,576,737
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	(150,000)	-
Outstanding as of September 30, 2012	1,106,627	1,106,627	4,085,160	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 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 company.

These warrants are not mandatorily redeemable, do not obligate the Company to repurchase its equity shares by transferring assets or issuing a variable number of shares. The warrants require that the Company deliver shares as part of a physical settlement or a net-share settlement, dependent on the warrant agreement, and do not provide for a net-cash settlement. All of the Company's warrants are classified as equity.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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18. Subsequent events

The Company has evaluated subsequent events through the date of issuance of the condensed consolidated financial statements. 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, (a) six months of his base salary payable over the six month period, (b) bonus payments of \$100,000 upon each of four bonus payment events tied to the Company’s clinical trial plan for the dermaPACE device, (c) a grant of 1,000,000 options to acquire shares of Common Stock with 600,000 options vested upon the execution of the Severance Agreement and the remaining 400,000 options vesting in increments of 100,000 upon each of the bonus payment events at subpart (b) above, and (d) a grant of 50,000 options to acquire shares of Common Stock as consideration for the provision of twelve months of advisory services. Payment of the foregoing severance amounts is subject to receipt and effectiveness of a release of claims against the Company. In addition, the Company vested all of Mr. Cashman’s outstanding stock options. The Company will record the effect of these transactions in the fourth quarter of 2012.

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, 2011 included in our Annual Report on Form 10-K filed with the SEC on March 14, 2012.

Overview

We are an emerging global regenerative medicine company focused on the development and commercialization of noninvasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. Our portfolio of products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions.

We believe we have demonstrated that our PACE technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States Food and Drug Administration (“FDA”) Class III Premarket Approval (“PMA”) 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, Canada and Asia. Our lead product candidate for the global wound care market, dermaPACE®, has received the European CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. We currently do not have any commercial products in the United States. Revenues are from sales of CE Marked devices and accessories in Europe, Canada and Asia.

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

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

Recent Developments

dermaPACE clinical trial

Our lead device product for the global wound care market, dermaPACE, has completed its pivotal Phase III, investigational device exemption (IDE) trial in the United States for the treatment of diabetic foot ulcers. 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, complete 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 ($p=0.018$); at 24 weeks dermaPACE achieved 40% complete wound closure in the ITT population ($p=0.054$) and 41% complete wound closure in the EE population ($p=0.022$).
- Subjects treated with dermaPACE achieved a significant increase in the rate of complete wound closure or $\geq 90\%$ wound area reduction by or at 12 weeks ($p<0.05$).
- 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% 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 third and final 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.

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In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's previously disclosed 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 is 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 plan to conduct additional clinical work to provide support for the FDA to approve the dermaPACE PMA.

We have finalized our clinical study plan and the FDA has granted conditional approval of our IDE supplement for an additional clinical trial. We estimate the clinical trial could be completed and submitted in support of a PMA application for dermaPACE in as early as 20 months from trial initiation, assuming such data to be collected meets the agreed upon statistical and clinical plan of success. We worked closely with the FDA to develop the protocol and statistical plan that were submitted in the IDE Supplement. 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 to bear on 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 clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the recently completed pivotal trial. Similar to the previous trial, four (4) dermaPACE procedures will be administered during the first two weeks following subject enrollment. In the upcoming trial, however, up to four (4) additional dermaPACE procedures will be delivered bi-weekly, between weeks 4 and 10, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

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. The first analysis for making a study success determination is projected to occur after 90 patients (approximately 45 per arm) have completed the 12-week primary efficacy evaluation period. If study data achieves pre-defined statistical and clinical success criteria associated with wound closure favoring dermaPACE, then the clinical trial can be stopped, and we will submit an amendment to the current PMA for approval. The controlled interim monitoring plan also includes a provision for DMC review of data prior to enrollment of the 90 subjects. This provision has been established in order to monitor the progress of the trial and ensure its alignment with our statistical plan, or to increase the sample size should additional subjects be needed to demonstrate study success, or stop the trial if study success is deemed unattainable. By monitoring the data in this way, appropriate steps can be taken 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.

We have already identified clinical study sites and are in the process of contracting with them for participation. Patient enrollment is expected to begin in the first quarter of 2013 once Institutional Review Board (IRB) approvals and appropriate funding to conduct the study are in place.

Efforts to raise capital

We are working with select accredited investors to raise up to \$1.25 million in capital in a private placement. The accredited investors will receive a convertible promissory note that will convert, at the Company's option, at the completion of a larger funding which is expected to close no later than the first quarter of 2013. If these efforts are

unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code.

Financial Overview

Our independent registered public accounting firm in 2011 has included a “going concern” statement in its report on our consolidated financial statements for the year ended December 31, 2011, stating that we had a net loss and negative cash flows from operations in fiscal 2011, and that we have an accumulated deficit. Accordingly, those conditions raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from this going concern uncertainty.

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 September 30, 2012, the balance of cash and cash equivalents totaled \$361,263.

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

Since our inception, we have incurred losses from operations each year. As of September 30, 2012, we had an accumulated deficit of \$69,216,040. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next few years as we continue to fund our research and development activities, clinical trials and the FDA approval process.

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 of our products;
- 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 the Company 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, 2011, filed with the SEC on March 14, 2012.

Critical Accounting Policies and Estimates

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

On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses, fair valuation of inventory, fair valuation of stock related to stock-based compensation and income taxes. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

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, 2011, filed with the SEC on March 14, 2012, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, stock-based compensation and income taxes are significant; therefore, they are important to aid investors in fully understanding and evaluating our reported financial results.

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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. Fees from services performed are recognized when the service is performed.

Research and Development Costs

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

Inventory Valuation

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

Inventory is valued using first in, first out ("FIFO"), and consists primarily of devices and the component material for assembly of finished products, less reserves for obsolescence.

Stock-based Compensation

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

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

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using weighted average assumptions amortized to expense over the options' vesting periods. These assumptions include the risk-free interest rate, expected dividend yield, volatility factor of the expected market price of our

Common Stock, forfeiture rate and weighted average expected life of the option. 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 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.

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 related to future years, including loss carryforwards, if there is not sufficient evidence to indicate that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in future years. We have recorded a full valuation allowance as of September 30, 2012 and December 31, 2011, 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.

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

Results of Operations for the Three Months ended September 30, 2012 and 2011 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended September 30, 2012 were \$178,256, compared to \$161,678 for the same period in 2011, an increase of \$16,578, or 10%. The increase in revenues is primarily due to increased sales of refurbishment applicators for devices due to the increased number of devices in use in 2012, as compared to 2011.

Cost of revenues for the three months ended September 30, 2012 was \$43,965, compared to \$48,475 for the same period in 2011. Gross profit as a percentage of revenues was 75% for the three months ended September 30, 2012, as compared to 70% for the same period in 2011. The increase in gross profit as a percentage of revenues was due to increased sales of higher margin refurbishment applicators in 2012, as compared to 2011.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2012 were \$440,193, compared to \$623,318 for the same period in 2011, a decrease of \$183,125, or 29%. Research and development expenses in 2012 decreased due to lower expenses for clinical results analysis and clinical related expenses as compared to same period in 2011.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2012 were \$977,859, compared to \$1,493,963 for the same period in 2011, a decrease of \$516,104, or 35%. General and administrative expenses include non-cash stock-based compensation of \$217,686 and \$250,177 for the three months ended September 30, 2012 and 2011, respectively. The decrease in non-cash stock-based compensation costs of \$32,491 in 2012 was primarily due to the full expense in September 2011 for certain stock options which were fully vested when granted.

Excluding the non-cash costs for stock-based compensation, general and administrative expenses were \$760,173 for the three months ended September 30, 2012, as compared to \$1,243,786 for the same period in 2011, a decrease of \$483,613, or 39%. The decrease in general and administrative expenses is primarily due to a reduction in headcount (18 employees in September 2012 as compared to 29 employees in September 2011), decreased investor relations expenses and decreased legal costs for patent defense activities.

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Other Income (Expense)

In June 2009, we sold our veterinary division to Pulse Veterinary Technologies, LLC (“Pulse Vet”). Under the 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 on November 1, 2011. The income for these transitional services was \$0 and \$112,500 for the three months ended September 30, 2012 and 2011, respectively.

Provision for Income Taxes

At September 30, 2012, we had federal net operating loss carryforwards of \$49,172,791 for tax years through the year ended December 31, 2011 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 September 30, 2012, 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 September 30, 2012 was \$1,447,271, or (\$0.07) per basic and diluted share, compared to a net loss of \$2,071,539, or (\$0.10) per basic and diluted share, for the same period in 2011, a decrease in the net loss of \$624,268, or 30%. We anticipate that our operating losses will continue over the next several years as we continue to fund our research and development activities including our clinical trials.

Results of Operations for the Nine Months ended September 30, 2012 and 2011 (Unaudited)

Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2012 were \$627,153, compared to \$577,180 for the same period in 2011, an increase of \$49,973, or 9%. The increase in revenues is primarily due to increased sales of demonstration devices and refurbishment applicators to European distributors in 2012, as compared to 2011.

Cost of revenues for the nine months ended September 30, 2012 was \$197,898, compared to \$189,006 for the same period in 2011. Gross profit as a percentage of revenues was 68% for the nine months ended September 30, 2012, as 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 refurbishment applicators in 2012, as compared to 2011.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2012 were \$1,391,634, compared to \$2,167,735 for the same period in 2011, a decrease of \$776,101, or 36%. 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.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2012 were \$3,252,127, compared to \$4,386,538 for the same period in 2011, a decrease of \$1,134,411, or 26%. General and administrative expenses include non-cash stock-based compensation of \$719,732 and \$550,387 for the nine months ended September 30, 2012 and 2011, respectively. The increase in non-cash stock-based compensation costs of \$169,345 in 2012 was primarily due to the employee stock options granted in October 2011 and the options granted to members of our medical advisory board in March 2012.

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Excluding the non-cash costs for stock-based compensation, general and administrative expenses were \$2,532,395 for the nine months ended September 30, 2012, as compared to \$3,836,151 for the same period in 2011, a decrease of \$1,303,756, or 34%. The decrease in general and administrative expenses is primarily due to a reduction in headcount (18 employees in September 2012 as compared to 29 employees in September 2011), decreased investor relations expenses and decreased legal costs for patent defense activities.

Other Income (Expense)

On April 4, 2011, we 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. In addition, 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. 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 the notes were exchanged for on the date of exchange as compared to the fair value of the notes, assuming the conversion feature was exercised by the noteholders.

In June 2009, we sold our veterinary division to Pulse Vet. Under the 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 on November 1, 2011. The income for these transitional services was \$0 and \$337,500 for the nine months ended September 30, 2012 and 2011, respectively.

Interest expense, net, for the nine months ended September 30, 2012 was \$241,196, compared to \$392,652 for the same period in 2011, a decrease of \$151,456, or 39%. The decrease was due to no interest expense for the nine months ended September 30, 2012 on certain notes payable to related parties as a result of the notes being exchanged for Common Stock and warrants on April 4, 2011 as discussed above.

Provision for Income Taxes

At September 30, 2012, we had federal net operating loss carryforwards of \$49,172,791 for tax years through the year ended December 31, 2011 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 September 30, 2012, 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 nine months ended September 30, 2012 was \$4,707,212, or (\$0.23) per basic and diluted share, compared to a net loss of \$7,827,072, or (\$0.41) per basic and diluted share, for the same period in 2011, a decrease in the net loss of \$3,119,860, or 40%. We anticipate that our operating losses will continue over the next several years as we continue to fund our research and development activities, including our clinical trials.

Liquidity and Capital Resources

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources to continue our research and development efforts, including clinical trials. Because of the significant time it

will take for our products to complete the clinical trial process, and for us to obtain approval from regulatory authorities and successfully commercialize our products, we will require substantial additional capital. We incurred a net loss of \$4,707,212 for the nine months ended September 30, 2012 and a net loss of \$10,238,797 for the year ended December 31, 2011. These operating losses create uncertainty about our ability to continue as a going concern. As of September 30, 2012, we had cash and cash equivalents of \$361,263. We are working with select accredited investors to raise up to \$1.25 million in capital in a private placement. The accredited investors will receive a convertible promissory note that will convert, at the Company's option, at the completion of a larger funding which is expected to close no later than the first quarter of 2013. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code.

We may be able to raise additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, or we may seek an investment by a strategic partner in a specific clinical indication or market opportunity, or we may sell all or a portion of the Company's assets. 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. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. 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 nine months ended September 30, 2012 and 2011, net cash used by operating activities was \$3,546,299 and \$6,994,179, 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 2012, as compared to the same period for 2011, of \$3,447,880, or 49%, was due to reductions in headcount, operating expenses and clinical expenses in 2012 as well as a reduction in current liabilities in 2011. Net cash provided (used) by financing activities for the nine months ended September 30, 2012 and 2011 was \$(3,399) and \$12,367,455, respectively, which in 2011 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 decreased by \$3,548,120 for the nine months ended September 30, 2012. Cash and cash equivalents increased by \$5,367,025 for the nine months ended September 30, 2011.

Segment and Geographic Information

We have determined that we are principally engaged in one operating segment. The Company's revenues are generated from sales in Europe, Canada and Asia.

Other Comprehensive Income (Loss)

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

Contractual Obligations

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

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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 Chairman of the Board of Directors (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 September 30, 2012. Based on this evaluation, the Chairman of the Board of Directors (principal executive officer) and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2012.

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
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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).
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3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
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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).

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.

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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: November 14, 2012

SANUWAVE HEALTH, INC.

By: /s/ Kevin A. Richardson, II
Kevin A. Richardson, II
Chairman of the Board of Directors (Principal 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/ Kevin A. Richardson, II Name: Kevin A. Richardson, II	Chairman of the Board of Directors (principal executive officer)	November 14, 2012
By: /s/ Barry J. Jenkins Name: Barry J. Jenkins	Chief Financial Officer (principal financial and accounting officer)	November 14, 2012
By: /s/ John F. Nemelka Name: John F. Nemelka	Director	November 14, 2012

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