

SANUWAVE Health, Inc.  
Form 10-Q  
November 14, 2011

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, 2011

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.)

11680 Great Oaks Way, Suite 350  
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

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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   
(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 8, 2011, there were issued and outstanding 20,907,536 shares of the registrant's common stock, \$.001 par value.

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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, 2010, filed on March 28, 2011 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, 2010, filed on March 28, 2011.

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. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2011 (Unaudited)	December 31, 2010 (Audited)
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 5,784,482	\$ 417,457
Accounts receivable - trade, net of allowance for doubtful accounts of \$62,629 in 2011 and \$36,903 in 2010	89,266	95,549
Inventory (Note 6)	425,663	463,643
Prepaid expenses	153,824	121,084
Due from Pulse Veterinary Technologies, LLC	130,039	45,389
<b>TOTAL CURRENT ASSETS</b>	<b>6,583,274</b>	<b>1,143,122</b>
<b>PROPERTY AND EQUIPMENT</b> , at cost, less accumulated depreciation (Note 7)	<b>36,601</b>	<b>13,386</b>
<b>OTHER ASSETS</b>	<b>32,386</b>	<b>32,253</b>
<b>INTANGIBLE ASSETS</b> , at cost, less accumulated amortization (Note 8)	<b>1,610,471</b>	<b>1,840,538</b>
<b>TOTAL ASSETS</b>	<b>\$ 8,262,732</b>	<b>\$ 3,029,299</b>
<b>LIABILITIES</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,161,384	\$ 1,829,815
Accrued employee compensation	472,638	1,101,410
Accrued expenses (Note 9)	181,368	256,204
Notes payable, related parties (Notes 4 and 11)	-	4,247,290
Interest payable, related parties (Note 11)	81,864	82,977
Liabilities related to discontinued operations	655,061	655,061
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,552,315</b>	<b>8,172,757</b>
<b>NOTES PAYABLE, RELATED PARTIES</b> (Note 11)	<b>5,372,743</b>	<b>5,372,743</b>
<b>TOTAL LIABILITIES</b>	<b>7,925,058</b>	<b>13,545,500</b>
<b>COMMITMENTS AND CONTINGENCIES</b> (Note 13)	<b>-</b>	<b>-</b>

GOING CONCERN (Note 3)	-	-
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
PREFERRED STOCK, par value \$0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-
COMMON STOCK, par value \$0.001, 50,000,000 shares authorized; 20,907,536 in 2011 and 14,794,650 in 2010 issued and outstanding (Note 4)	20,908	14,795
ADDITIONAL PAID-IN CAPITAL	62,372,551	43,728,133
ACCUMULATED OTHER COMPREHENSIVE INCOME	41,318	10,902
RETAINED DEFICIT	(62,097,103 )	(54,270,031 )
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>337,674</b>	<b>(10,516,201 )</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$ 8,262,732</b>	<b>\$ 3,029,299</b>

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, 2011	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
REVENUES	\$ 161,678	\$ 278,212	\$ 577,180	\$ 538,540
COST OF REVENUES	48,475	109,801	189,006	198,381
GROSS PROFIT	113,203	168,411	388,174	340,159
OPERATING EXPENSES				
Research and development	623,318	1,000,265	2,167,735	2,981,890
General and administrative	1,493,963	1,393,826	4,386,538	4,490,586
Depreciation	971	155,198	13,452	535,132
Amortization	76,689	76,689	230,067	230,068
TOTAL OPERATING EXPENSES	2,194,941	2,625,978	6,797,792	8,237,676
OPERATING LOSS	(2,081,738 )	(2,457,567 )	(6,409,618 )	(7,897,517 )
OTHER INCOME (EXPENSE)				
Transitional services provided to Pulse Veterinary Technologies, LLC	112,500	90,000	337,500	270,125
Gain on sale of assets	-	4,500	-	6,565
Extinguishment of debt (Note 11)	-	-	(1,318,781 )	-
Interest expense, net	(76,578 )	(274,247 )	(392,652 )	(731,771 )
Loss on foreign currency exchange	(25,723 )	(25,877 )	(43,521 )	(32,498 )
TOTAL OTHER INCOME (EXPENSE)	10,199	(205,624 )	(1,417,454 )	(487,579 )
LOSS BEFORE INCOME TAXES	(2,071,539 )	(2,663,191 )	(7,827,072 )	(8,385,096 )
INCOME TAX EXPENSE	-	-	-	-
NET LOSS	(2,071,539 )	(2,663,191 )	(7,827,072 )	(8,385,096 )
OTHER COMPREHENSIVE INCOME (LOSS)				

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Foreign currency translation adjustments	17,128	(12,520 )	30,416	(16,681 )
<b>TOTAL COMPREHENSIVE LOSS</b>	<b>\$ (2,054,411 )</b>	<b>\$ (2,675,711 )</b>	<b>\$ (7,796,656 )</b>	<b>\$ (8,401,777 )</b>

**LOSS PER SHARE:**

Net loss - basic	\$ (0.10 )	\$ (0.21 )	\$ (0.41 )	\$ (0.67 )
Net loss - diluted	\$ (0.10 )	\$ (0.21 )	\$ (0.41 )	\$ (0.67 )

Weighted average shares outstanding - basic	20,907,536	12,511,879	19,196,236	12,510,398
Weighted average shares outstanding - diluted	20,907,536	12,511,879	19,196,236	12,510,398

See accompanying notes to unaudited condensed consolidated financial statements.



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

	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (7,827,072 )	\$ (8,385,096 )
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization	230,067	230,068
Accrued interest	166,618	734,697
Depreciation	13,452	535,132
Change in allowance for doubtful accounts	25,726	8,807
Gain on sale of property and equipment	-	(6,565 )
Stock-based compensation	550,387	1,389,647
Extinguishment of debt	1,318,781	-
Changes in assets - (increase)/decrease		
Accounts receivable - trade	(19,443 )	(15,914 )
Inventory	37,980	108,127
Prepaid expenses	(32,740 )	(9,455 )
Due from Pulse Veterinary Technologies, LLC	(84,650 )	57,693
Other assets	(133 )	55
Assets held for sale	-	(1,316 )
Changes in liabilities - increase/(decrease)		
Accounts payable	(668,431 )	1,041,160
Accrued employee compensation	(628,772 )	449,371
Accrued expenses	(74,836 )	(269,960 )
Interest payable, related parties	(1,113 )	-
<b>NET CASH USED BY OPERATING ACTIVITIES</b>	<b>(6,994,179 )</b>	<b>(4,133,549 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Proceeds from sale of property and equipment	-	7,000
Purchase of property and equipment	(36,667 )	-
<b>NET CASH PROVIDED (USED) BY INVESTING ACTIVITIES</b>	<b>(36,667 )</b>	<b>7,000</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
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	-
Proceeds from promissory notes, related parties	-	2,450,000
Proceeds from sale of common stock	-	300,000

NET CASH PROVIDED BY FINANCING ACTIVITIES	12,367,455	2,750,000
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS	30,416	(16,681 )
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,367,025	(1,393,230 )
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	417,457	1,786,369
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 5,784,482	\$ 393,139
SUPPLEMENTAL INFORMATION		
Cash paid for interest	\$ 242,903	\$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Capital stock issued in exchange for notes payable, related parties (Notes 4 and 11)	\$ 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, 2011

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.

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, 2011 and for the three and nine months ended September 30, 2011 and 2010 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, 2011 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2011.

The condensed consolidated balance sheet at December 31, 2010 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, 2010, filed with the Securities and Exchange Commission (the “SEC”) on March 28, 2011. 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

As shown in the accompanying condensed consolidated financial statements, the Company incurred a net loss of \$7,827,072 and \$8,385,096 for the nine months ended September 30, 2011 and 2010, respectively. These operating losses create an uncertainty about the Company’s ability to continue as a going concern. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing will 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.



SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2011

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 agreed, pursuant to the terms of a registration rights agreement with the investors, to file 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. The Company also agreed to keep the registration statement effective until all registrable securities are sold or may be sold pursuant to Rule 144 under the Securities Act. If the Company is unable to comply with this covenant, the Company will be required to pay liquidated damages to the investors in the amount of 2.0% of the investors’ purchase price per month during such non-compliance (capped at a maximum of 12% of the purchase price), with such liquidated damages payable in cash. The Company filed the registration statement on May 10, 2011, and the registration statement was declared effective by the SEC on June 28, 2011. We evaluated any liability under the registration rights agreement at September 30, 2011 and determined no accrual was necessary.

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

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 (as described below) 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.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2011

4. Equity transactions (continued)

Each “Unit” 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 the transaction, at the purchase price of \$2.00 per Unit.

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 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 for a number of Units equal to (i) the unpaid principal and interest on each such note, divided by (ii) 2. The unpaid principal and interest on the notes totaled \$2,517,660, and this sum was exchanged for 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. In accordance with ASC 470, “Debt”, in October 2010, the Company recorded a loss from extinguishment of debt of \$2,693,896, which was the difference between the estimated fair value of the Units on the date of exchange of \$5,211,556 and the carrying value of the promissory notes of \$2,517,660.

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, 2011	December 31, 2010
Inventory - finished goods	\$ 481,809	\$ 539,141
Inventory - parts	85,754	78,202
<b>Total</b>	<b>567,563</b>	<b>617,343</b>

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Provision for losses and obsolescence	(141,900 )	(153,700 )
Net inventory	\$ 425,663	\$ 463,643

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2011

## 7. Property and equipment

Property and equipment consists of the following:

	September 30, 2011	December 31, 2010
Machines and equipment	\$ 229,906	\$ 199,520
Office and computer equipment	298,036	296,120
Leasehold improvements	67,421	67,421
Furniture and fixtures	24,613	24,613
Vehicles	22,531	22,531
Software	40,233	40,233
Other assets	2,391	5,080
Construction in progress	4,365	-
Total	689,496	655,518
Accumulated depreciation	(652,895 )	(642,132 )
Net property and equipment	\$ 36,601	\$ 13,386

The aggregate depreciation related to property and equipment charged to operations was \$971 and \$15,886 for the three months ended September 30, 2011 and 2010, respectively, and \$13,452 and \$66,815 for the nine months ended September 30, 2011 and 2010, respectively.

## 8. Intangible assets

Intangible assets consist of the following:

	September 30, 2011	December 31, 2010
Patents, at cost	\$ 3,502,135	\$ 3,502,135
Less accumulated amortization	(1,891,664)	(1,661,597)
Net intangible assets	\$ 1,610,471	\$ 1,840,538

The aggregate amortization charged to operations was \$76,689 and \$76,689 for the three months ended September 30, 2011 and 2010, respectively, and \$230,067 and \$230,068 for the nine months ended September 30, 2011 and 2010, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2011

## 9. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2011	December 31, 2010
Accrued legal professional fees	\$ 78,099	\$ 64,531
Accrued audit and tax preparation	67,388	89,173
Accrued clinical site payments	-	82,500
Accrued other	35,881	20,000
	\$ 181,368	\$ 256,204

## 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 September 30, 2011, the Company had federal net operating loss (“NOL”) carryforwards of \$40,896,849 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, 2011 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2011. 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  
September 30, 2011

## 11. Notes payable, related parties

The notes payable consist of the following:

	September 30, 2011	December 31, 2010
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 and \$82,977 at September 30, 2011 and December 31, 2010, respectively. Accrued interest not payable until August 1, 2015 totaled \$1,372,743 at September 30, 2011 and December 31, 2010.	\$ 5,372,743	\$ 5,372,743
Notes payable, unsecured, bearing interest at 15% to Prides Capital Fund I, LP and NightWatch Capital Partners II, LP, shareholders of the Company. Accrued interest totaled \$1,047,290 at December 31, 2010. On April 4, 2011, the notes were cancelled in consideration of the issuance of shares of Common Stock and warrants of the Company.	-	4,247,290
<b>Total</b>	<b>5,372,743</b>	<b>9,620,033</b>
Less current portion	-	(4,247,290 )
<b>Non-current portion</b>	<b>\$ 5,372,743</b>	<b>\$ 5,372,743</b>

Interest expense on notes payable to related parties totaled \$81,864 and \$232,112 for the three months ended September 30, 2011 and 2010, respectively, and \$408,408 and \$673,809 for the nine months ended September 30, 2011 and 2010, respectively.

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.

## 12. 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.

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

As a result of the net loss for the three and nine months ended September 30, 2011 and 2010, 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 12,184,577 shares and 4,875,659 shares at September 30, 2011 and 2010, respectively.

13. Commitments and contingencies

Operating Leases

The Company leases office and warehouse space. Rent expense for the three months ended September 30, 2011 and 2010, was \$87,312 and \$83,908, respectively, and \$262,194 and \$254,190 for the nine months ended September 30, 2011 and 2010, 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.

14. 401(k) plan

The Company sponsors a 401(k) plan that covers all employees who meet the eligibility requirements. The Company matches 50% of employee contributions up to 6% of their compensation. The Company contributed \$19,535 and \$18,310 to the plan for the three months ended September 30, 2011 and 2010, respectively, and \$55,937 and \$53,094 for the nine months ended September 30, 2011 and 2010, 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 "Amended Plan"). The Amended Plan permits grants of awards to selected employees and directors of the Company in the form of restricted stock or options to purchase shares of Common Stock. 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 Company recognized as compensation cost for all outstanding stock options, restricted stock and warrants granted to employees and directors, \$250,177 and \$451,947 for the three months ended September 30, 2011 and 2010, respectively, and \$550,387 and \$1,389,647 for the nine months ended September 30, 2011 and 2010, respectively.



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

A summary of option activity as of September 30, 2011 and December 31, 2010, and the changes during the three and nine months ended September 30, 2011, is presented as follows:

	Options	Weighted Average Exercise Price
Outstanding as of December 31, 2010	2,992,796	\$ 3.20
Granted	-	\$ -
Exercised	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of March 31, 2011	2,992,796	\$ 3.20
Granted	-	\$ -
Exercised	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of June 30, 2011	2,992,796	\$ 3.20
Granted	50,000	\$ 2.90
Exercised	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of September 30, 2011	3,042,796	\$ 3.19
Exercisable	2,209,425	\$ 2.60

The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on September 30, 2011 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders, had all option holders been able to, and in fact had, exercised their options on September 30, 2011. The aggregate intrinsic value of the outstanding stock options at September 30, 2011 was \$638,400. The aggregate intrinsic value of the exercisable outstanding stock options at September 30, 2011 was \$583,363.

The weighted average remaining contractual term for outstanding and exercisable stock options was 6.5 years as of September 30, 2011, and 7.1 years as of December 31, 2010.

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

A summary of the Company's nonvested options as of September 30, 2011 and December 31, 2010, and changes during the three and nine months ended September 30, 2011, is presented as follows:

	Options	Weighted Average Grant-Date Fair Value
Outstanding as of December 31, 2010	883,993	\$ 1.67
Granted	-	\$ -
Vested	(26,562 )	\$ 2.51
Forfeited or expired	-	\$ -
Outstanding as of March 31, 2011	857,431	\$ 1.65
Granted	-	\$ -
Vested	(11,560 )	\$ 1.75
Forfeited or expired	-	\$ -
Outstanding as of June 30, 2011	845,871	\$ 1.65
Granted	50,000	\$ 2.11
Vested	(62,500 )	\$ 2.04
Forfeited or expired	-	\$ -
Outstanding as of September 30, 2011	833,371	\$ 1.64

A summary of the Company's restricted stock as of September 30, 2011 and December 31, 2010, and changes during the three and nine months ended September 30, 2011, is presented as follows:

	Restricted Stock	Weighted Average Grant-Date Fair Value
Outstanding as of December 31, 2010	403,030	\$ 2.92
Granted	-	\$ -
Vested	(403,030 )	\$ 2.92
Forfeited or expired	-	\$ -
Outstanding as of March 31, 2011	-	\$ -
Granted	-	\$ -
Vested	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of June 30, 2011	-	\$ -
Granted	-	\$ -
Vested	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of September 30, 2011	-	\$ -





SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
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## 16. Warrants

A summary of the warrant activity as of September 30, 2011 and December 31, 2010, and the changes during the three and nine months ended September 30, 2011, is presented as follows:

	Class A Warrants	Class B Warrants	Class D Warrants	Class E Warrants
Outstanding as of December 31, 2010	1,106,627	1,106,627	2,284,993	-
Issued	-	-	1,950,167	-
Exercised	-	-	-	-
Cancelled	-	-	-	-
Outstanding as of March 31, 2011	1,106,627	1,106,627	4,235,160	-
Issued	-	-	-	3,576,737
Exercised	-	-	-	-
Cancelled	-	-	-	-
Outstanding as of June 30, 2011	1,106,627	1,106,627	4,235,160	3,576,737
Issued	-	-	-	-
Exercised	-	-	-	-
Cancelled	-	-	-	-
Outstanding as of September 30, 2011	1,106,627	1,106,627	4,235,160	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.

## 17. Subsequent events

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

## 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, 2010 included in our Annual Report on Form 10-K filed with the SEC on March 28, 2011.

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## 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. 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.

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

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

## Recent Developments

We have completed our multi-site, randomized, double-blind, sham controlled FDA investigational device exemption wound care clinical study focused on the healing of diabetic foot ulcers utilizing our lead product candidate, dermaPACE, and submitted to the FDA the third and final module of the Premarket Approval ("PMA") application. The primary study goal is to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to Sham-control, when both are combined with the current standard of care. The standard of care includes wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

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.
- 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.
- 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 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 expect, pending a favorable response from the FDA, to launch dermaPACE in the United States in 2012.

#### Financial Overview

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

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

On April 4, 2011, the noteholders (the “Noteholders”) of our amended senior notes (the “Notes”) exchanged the unpaid principal and interest balance of the Notes, which totaled \$4,413,908, for the issuance of 1,358,126 shares of our Common Stock. In connection with this transaction, we issued to the Noteholders warrants to purchase an aggregate of 679,064 shares of Common Stock at an exercise price of \$4.00 per share. The warrants vested upon issuance and expire after five years.

In January 2011, we raised \$3,900,334 from a group of accredited investors through the exercise of options they received in 2010 as part of a purchase of a Unit. In connection with the exercise of the options in January 2011, we issued 1,950,167 shares of our Common Stock and 1,950,167 Class D warrants.

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, 2011, the balance of cash and cash equivalents totaled \$5,784,482.

We continue to incur research and development expenses for clinical trials and the development of products for additional indications. We expect to continue to incur significant research and development expenses as a result of new and ongoing clinical and pre-clinical studies in the United States and in Europe, as well as expenses associated

with regulatory filings. In addition, we anticipate that our general and administrative expenses will continue to increase as we expand our operations, facilities and other administrative activities related to our efforts to bring our product candidates to commercialization. We will require additional capital to continue to implement our business strategies. There can be no assurance that we will be successful in raising such capital. See “Liquidity and Capital Resources.”

Since our inception, we have incurred losses from operations each year. As of September 30, 2011, we had an accumulated deficit of \$62.1 million. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next few years as we continue to fund our research and development activities, clinical trials and the FDA approval process and as we prepare for a future sales network to market our products.

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 timing and results of our pre-clinical research programs;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior.

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, 2010, filed with the SEC on March 28, 2011.

#### 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 1 to our consolidated financial statements filed with our Annual Report on Form 10-K for the year ended December 31, 2010, filed with the SEC on March 28, 2011, 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 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. Fees from services performed are recognized when the service is performed.





### Research and Development Costs

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

### Inventory Valuation

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

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

### Stock-based Compensation

On November 1, 2010, the board of directors of the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the “Amended Plan”). The Amended Plan provides that stock options, and other equity interests or equity-based incentives, may be granted to key personnel and directors at 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.

### Income Taxes

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

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

Results of Operations for the Three Months ended September 30, 2011 and 2010 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended September 30, 2011 were \$161,678, compared to \$278,212 for the same period in 2010, a decrease of \$116,534, or 42%. In July 2010 we introduced in Europe our new product, orthoPACE, for orthopedic, trauma and sports medicine indications. The revenues for the three months ended September 30, 2010 included \$98,143 in one-time sales of demonstration orthoPACE devices to our European distributors for this newly introduced product.

Cost of revenues for the three months ended September 30, 2011 was \$48,475, compared to \$109,801 for the same period in 2010. Gross profit as a percentage of revenues was 70% for the three months ended September 30, 2011, as compared to 61% for the same period in 2010. The increase in gross profit as a percentage of revenues was due to lower margin sales of the new orthoPACE demonstration devices in 2010.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2011 were \$623,318, compared to \$1,000,265 for the same period in 2010, a decrease of \$376,947, or 38%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical related consultants, contract manufacturer development costs and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs. Research and development expenses decreased due to lower expenses related to clinical site payments, clinical monitoring and clinical database costs for the clinical trial of dermaPACE for treating diabetic foot ulcers in the United States as enrollment and patient follow-up ended during 2010 and the costs for 2011 transitioned to clinical results analysis.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2011 were \$1,493,963, compared to \$1,393,826 for the same period in 2010, an increase of \$100,137, or 7%. General and administrative expenses include the non-cash costs for stock-based compensation of \$250,177 and \$451,947 for the three months ended September 30, 2011 and 2010, respectively. The decrease in non-cash compensation costs for stock compensation of \$201,770 was primarily due to the restricted stock granted in 2009 becoming fully vested and expensed as of January 1, 2011.

Excluding the non-cash costs for stock-based compensation, general and administrative expenses were \$1,243,786 for the three months ended September 30, 2011, as compared to \$941,879 for the same period in 2010, an increase of \$301,907, or 32%. The increase in general and administrative expenses is primarily due to increased sales and marketing expenses for medical society tradeshow for dermaPACE and increased legal costs as a result of patent preparation, filing and defense activities.

Depreciation and Amortization

Depreciation for the three months ended September 30, 2011 was \$971, compared to \$155,198 for the same period in 2010, a decrease of \$154,227, or 99%. The decrease was primarily due to depreciation expense of \$139,312 for the three months ended September 30, 2010 on assets held for sale. There was no depreciation expense for the three months ended September 30, 2011 on assets held for sale. As of December 31, 2010, the assets held for sale were

fully depreciated as management determined that the market for selling the used Ossatron mobile service devices, which were classified as held for sale, was not probable due to the age of the devices.

Amortization of intangible assets for the three months ended September 30, 2011 and 2010 was \$76,689.

Other Income (Expense)

On June 3, 2009, we sold our veterinary division to Pulse Veterinary Technologies, LLC (“Pulse Vet”). Under terms of the asset purchase agreement, we will continue to provide production services at the direction of Pulse Vet for a fee until April 30, 2012, unless Pulse Vet elects to terminate the agreement at an earlier date. We received notification from Pulse Vet of their intention to terminate this agreement effective October 31, 2011. The income for these transitional services was \$112,500 and \$90,000 for the three months ended September 30, 2011 and 2010, respectively, an increase of \$22,500 or 25%. The increase was due to the contractual increase in fees for the monthly production services effective January 1, 2011.

Interest expense, net, for the three months ended September 30, 2011 was \$76,578, compared to \$274,247 for the same period in 2010, a decrease of \$197,669, or 72%. The decrease was due to no interest expense for the three months ended September 30, 2011 on certain notes payable to related parties as a result of the note exchange for Common Stock and warrants on April 4, 2011.

#### Provision for Income Taxes

At September 30, 2011, we had federal net operating loss carryforwards of approximately \$40.9 million that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

#### Net Loss

Net loss for the three months ended September 30, 2011 was \$2,071,539, or (\$0.10) per basic and diluted share, compared to a net loss of \$2,663,191, or (\$0.21) per basic and diluted share, for the three months ended September 30, 2010. We anticipate that our operating losses will continue over the next several years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to market our products.

#### Results of Operations for the Nine Months ended September 30, 2011 and 2010 (Unaudited)

##### Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2011 were \$577,180, compared to \$538,540 for the same period in 2010, an increase of \$38,640, or 7%. The increase in revenues was a result of sales in Europe of our new product, orthoPACE, for orthopedic, trauma and sports medicine indications, which was introduced in July 2010.

Cost of revenues for the nine months ended September 30, 2011 was \$189,006, compared to \$198,381 for the same period in 2010. Gross profit, as a percentage of revenues, was 67% for the nine months ended September 30, 2011, as compared to 63% for the same period in 2010. The increase in gross profit as a percentage of revenues was due to lower margin sales of the new orthoPACE demonstration devices in 2010.

##### Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2011 were \$2,167,735, compared to \$2,981,890 for the same period in 2010, a decrease of \$814,155, or 27%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical related consultants, contract manufacturer development costs and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs. Research and development expenses decreased due to lower expenses related to clinical site payments, clinical monitoring and clinical database costs for the clinical trial of dermaPACE for treating diabetic foot ulcers in the United States as enrollment and patient follow-up ended during 2010 and the costs for 2011 transitioned to clinical results analysis.

##### General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2011 were \$4,386,538, compared to \$4,490,586 for the same period in 2010, a decrease of \$104,048, or 2%. General and administrative expenses include the non-cash costs for stock-based compensation of \$550,387 and \$1,389,647 for the nine months ended September 30, 2011 and 2010, respectively. The decrease in non-cash compensation costs for stock compensation of \$839,260 was primarily due to the restricted stock granted in 2009 becoming fully vested and expensed as of January 1, 2011.

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Excluding the non-cash costs for stock-based compensation, general and administrative expenses were \$3,836,151 for the nine months ended September 30, 2011, as compared to \$3,100,939 for the same period in 2010, an increase of \$735,212, or 24%. The increase in general and administrative expenses is primarily due to increased sales and marketing expenses for medical society tradeshow, increased investor relations expenses and increased legal costs as a result of patent preparation, filing and defense activities.

#### Depreciation and Amortization

Depreciation for the nine months ended September 30, 2011 was \$13,452, compared to \$535,132 for the same period in 2010, a decrease of \$521,680, or 97%. The decrease was primarily due to depreciation expense of \$468,318 for the nine months ended September 30, 2010 on assets held for sale. There was no depreciation expense for the nine months ended September 30, 2011 on assets held for sale. As of December 31, 2010, the assets held for sale were fully depreciated as management determined that the market for selling the used Ossatron mobile service devices, which were classified as held for sale, was not probable due to the age of the devices.

Amortization of intangible assets for the nine months ended September 30, 2011 was \$230,067, compared to \$230,068 for the same period in 2010.

#### Other Income (Expense)

On June 3, 2009, we sold our veterinary division to Pulse Vet. Under terms of the asset purchase agreement, we will continue to provide production services at the direction of Pulse Vet for a fee until April 30, 2012, unless Pulse Vet elects to terminate the agreement at an earlier date. We received notification from Pulse Vet of their intention to terminate this agreement effective October 31, 2011. The income for these transitional services was \$337,500 and \$270,125 for the nine months ended September 30, 2011 and 2010, respectively, an increase of \$67,375 or 25%. The increase was due to the contractual increase in fees for the monthly production services effective January 1, 2011.

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 warrants to purchase an aggregate of 679,064 shares of Common Stock at an exercise price of \$4.00 per share. We recorded a loss from extinguishment of debt of \$1,318,781, which was the difference between the estimated fair value of the Common Stock and warrants on the date of exchange and the fair value of the notes (assuming the conversion feature was exercised by the noteholders).

Interest expense, net, for the nine months ended September 30, 2011 was \$392,652, compared to \$731,771 for the same period in 2010, a decrease of \$339,119, or 46%. The decrease was due to no interest expense after April 4, 2011 on certain notes payable to related parties as a result of the note exchange for Common Stock and warrants on that date.

#### Provision for Income Taxes

At September 30, 2011, we had federal net operating loss carryforwards of approximately \$40.9 million that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

#### Net Loss



Net loss for the nine months ended September 30, 2011 was \$7,827,072, or (\$0.41) per basic and diluted share, compared to a net loss of \$8,385,096, or (\$0.67) per basic and diluted share, for the nine months ended September 30, 2010. We anticipate that our operating losses will continue over the next several years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to market our products.

## Liquidity and Capital Resources

We incurred a net loss of \$7,827,072 and \$8,385,096 for the nine months ended September 30, 2011 and 2010, respectively. These operating losses create uncertainty about our ability to continue as a going concern. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing will provide the necessary funding for the Company to continue as a going concern. Our condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. At September 30, 2011, we had \$5,784,482 in cash and cash equivalents held in three financial institutions.

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 additional capital resources. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control.

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

For the nine months ended September 30, 2011, net cash used by operating activities was \$6,994,179, primarily consisting of compensation costs, clinical trials, research and development activities and general corporate operations. The net cash used by operating activities during the period included payments to reduce current payables, accrued employee compensation and accrued expenses which totaled \$1,372,039. Net cash used by investing activities for the nine months ended September 30, 2011 was \$36,667, which consisted of the purchase of fixed assets used for research and development and marketing purposes. Net cash provided by financing activities for the nine months ended September 30, 2011 was \$12,367,455, which consisted of the net proceeds from the private placement of \$8,467,121 and the exercise of unit options of \$3,900,334. Cash and cash equivalents increased by \$5,367,025 for the nine months ended September 30, 2011.

For the nine months ended September 30, 2010, net cash used by operating activities was \$4,133,549, primarily consisting of compensation costs, clinical trials, research and development activities and general corporate operations. Net cash provided by financing activities for the nine months ended September 30, 2010 was \$2,750,000, which consisted of the proceeds from the issuance of promissory notes of \$2,450,000 and from the sale of Common Stock of \$300,000. Cash and cash equivalents decreased by \$1,393,230 for the nine months ended September 30, 2010.

## 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.

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.

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

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.

We agreed, pursuant to the terms of a registration rights agreement with the investors, to file 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. We also agreed to keep the registration statement effective until all registrable securities are sold or may be sold pursuant to Rule 144 under the Securities Act. If we are unable to comply with this covenant, we will be required to pay liquidated damages to the investors in the amount of 2.0% of the investors' purchase price per month during such non-compliance (capped at a maximum of 12% of the purchase price), with such liquidated damages payable in cash. We filed the registration statement on May 10, 2011 and the registration statement was declared effective by the SEC on June 28, 2011. We evaluated any liability under the registration rights agreement at September 30, 2011 and determined no accrual was necessary.

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

### 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.

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#### 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 September 30, 2011. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2011.

The Company had previously reported, as of December 31, 2010, a material weakness in the Company’s internal control over financial reporting attributable to the lack of internal expertise and resources to analyze and properly apply United States generally accepted accounting principles to complex and non-routine transactions related to the appropriate treatments of complex financial instruments, derivatives and stock-based compensation. A “material weakness” is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis by the company’s internal controls. Management believes the material weakness identified above was due to the complex and non-routine nature of the Company’s complex financial instruments, derivatives and stock-based compensation.

##### Management Plan to Remediate Material Weaknesses

Management has developed a remediation plan to address the material weakness related to its processes and procedures surrounding its complex and non routine transactions, including the accounting for non-cash stock-based compensation expense. Implementation of the remediation plan consists of, among other things, redesigning the procedures to enhance its identification, capture, review, approval and recording of contractual terms, including equity arrangements. Management is also pursuing engaging, as necessary, an outside consultant to assist in the application of United States generally accepted accounting principles to complex transactions, including the accounting for complex financial instruments, derivatives and stock-based compensation. These measures are intended both to address the identified material weakness and to enhance our overall internal control environment.

##### 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, except as discussed above.

## 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).
- 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 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 Chief Executive Officer.
- 31.2\* Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
- 32.1\* Section 1350 Certification of the Chief 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

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\* 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, 2011

SANUWAVE HEALTH, INC.

By: /s/ Christopher M. Cashman  
Christopher M. Cashman  
Chief Executive Officer and President