SANUWAVE Health, Inc. Form 10-Q November 12, 2010

# 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, 2010

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_ Commission File Number 000-52985 SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

Nevada

20-1176000

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

11680 Great Oaks Way, Suite 350 Alpharetta, GA 30022

(Zip Code)

(Address of principal executive offices)

(678) 581-6843

(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. b Yes o 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). o Yes o No

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

Large accelerated filer o

Accelerated filer o

Non-accelerated filer o

Smaller reporting

(Do not check if a smaller reporting company)

company b

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

As of November 8, 2010, there were issued and outstanding 14,168,487 shares of the registrant s common stock.

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#### **Special Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-O 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. 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, 2009, filed on March 31, 2010. 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, 2009, filed on March 31, 2010.

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.

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## PART I FINANCIAL INFORMATION

# Item 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

	Se	September 30, 2010		ecember 31, 2009
	(	(Unaudited)	(	(Audited)
ASSETS				
CURRENT ASSETS Cash and cash equivalents Accounts receivable trade, net of allowance for doubtful accounts of \$29,569 in	\$	393,139	\$	1,786,369
2010 and \$20,762 in 2009		55,073		47,966
Inventory (Note 9) Prepaid expenses		484,462 130,612		592,589 121,157
Due from Pulse Veterinary Technologies, LLC		70,185		127,878
TOTAL CURRENT ASSETS		1,133,471		2,675,959
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note		21.456		00.707
10)		21,456		88,706
OTHER ASSETS		32,114		32,169
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 11)		1,917,227		2,147,295
ASSETS HELD FOR SALE (Note 8)		455,955		922,956
TOTAL ASSETS	\$	3,560,223	\$	5,867,085
LIABILITIES				
CURRENT LIABILITIES				
Accounts payable	\$	2,110,583	\$	1,069,423
Payroll and related Accrued expenses (Note 12)		959,276 359,069		509,905 629,029
Promissory notes (Note 14)		2,510,888		029,029
Notes payable, related parties (Note 15)		4,107,182		
Interest payable on notes payable, related parties (Note 15)		81,864		
Liabilities related to discontinued operations (Note 7)		655,061		655,061
TOTAL CURRENT LIABILITIES		10,783,923		2,863,418
NOTES PAYABLE, RELATED PARTIES (Note 15)		5,372,744		8,887,981
TOTAL LIABILITIES		16,156,667		11,751,399

COMMITMENTS AND CONTINGENCIES (Note 17)

# GOING CONCERN (Note 3)

# STOCKHOLDERS DEFICIT

COMMON STOCK, par value \$0.001, 50,000,000 shares authorized, 12,659,657 in 2010 and 12,509,657 in 2009 issued and outstanding	12,660	12,510
ADDITIONAL PAID-IN CAPITAL	34,431,090	32,741,593
ACCUMULATED OTHER COMPREHENSIVE LOSS	5,183	21,864
RETAINED DEFICIT	(47,045,377)	(38,660,281)
TOTAL STOCKHOLDERS DEFICIT	(12,596,444)	(5,884,314)
TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT	\$ 3,560,223	\$ 5,867,085

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30, 2010	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009
REVENUES	\$ 278,212	\$ 134,771	\$ 538,540	\$ 538,818
COST OF REVENUES	109,801	30,753	198,381	129,416
GROSS PROFIT	168,411	104,018	340,159	409,402
OPERATING EXPENSES				
Research and development	1,000,265	1,063,875	2,981,890	2,686,160
General and administrative	1,393,826	1,530,281	4,490,586	3,433,448
Depreciation	155,198	46,636	535,132	150,482
Amortization	76,689	76,689	230,068	230,067
TOTAL OPERATING EXPENSES	2,625,978	2,717,481	8,237,676	6,500,157
OPERATING LOSS	(2,457,567)	(2,613,463)	(7,897,517)	(6,090,755)
OTHER INCOME (EXPENSE)				
Gain/(loss) on sale of assets	4,500	9,142	6,565	(4,509)
Transitional services provided to Pulse				
Veterinary Technologies, LLC	90,000	102,500	270,125	136,250
Interest expense, net	(274,247)	(188,279)	(731,771)	(517,354)
Loss on foreign currency exchange	(25,877)		(32,498)	
TOTAL OTHER INCOME (EXPENSE)	(205,624)	(83,292)	(487,579)	(430,041)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES INCOME TAX EXPENSE	(2,663,191)	(2,696,755)	(8,385,096)	(6,520,796)
LOSS FROM CONTINUING OPERATIONS	(2,663,191)	(2,696,755)	(8,385,096)	(6,520,796)

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DISCONTINUED OPERATIONS Income from discontinued operations,				
net of tax Gain/(loss) on sale of veterinary				581,306
division, net of tax		(3,245)		2,489,028
INCOME (LOSS) FROM DISCONTINUED OPERATIONS		(3,245)		3,070,334
NET LOSS	(2,663,191)	(2,700,000)	(8,385,096)	(3,450,462)
OTHER COMPREHENSIVE INCOME (LOSS), net of tax				
Foreign currency translation adjustments	(12,520)	13,555	(16,681)	(33,671)
TOTAL COMPREHENSIVE INCOME (LOSS) \$	(2,675,711) \$	(2,686,445) \$	(8,401,777) \$	(3,484,133)
EARNINGS (LOSS) PER SHARE: Loss from continuing operations basic \$	(0.21) \$	(0.24) \$	(0.67) \$	6 (0.59)
Loss from continuing operations diluted\$	(0.21) \$	(0.24) \$	(0.67) \$	(0.59)
Income from discontinued operations basic \$	\$	\$	\$	0.28
Income from discontinued operations diluted \$	\$	\$	\$	0.28
Net loss basic \$	(0.21) \$	(0.24) \$	(0.67) \$	(0.31)
Net loss diluted \$	(0.21) \$	(0.24) \$	(0.67) \$	(0.31)
Weighted average shares outstanding basic	12,511,879	11,092,990	12,510,398	11,037,435
Weighted average shares outstanding diluted	12,511,879	11,092,990	12,510,398	11,037,435

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, 2010	Nine Months Ended September 30, 2009
CASH FLOWS FROM OPERATING ACTIVITIES  Net loss from continuing operations	\$ (8,385,096)	\$ (6,520,796)
Adjustments to reconcile net loss from continuing operations to net		
cash used by operating activities	220.000	220.067
Amortization	230,068	230,067
Accrued interest	734,697	527,739
Depreciation Change in allowance for doubtful accounts	535,132 8,807	150,482
Change in allowance for doubtful accounts (Gain) loss on sale of property and equipment	(6,565)	(38,128) 4,509
Stock-based compensation	1,389,647	585,400
Changes in assets (increase)/decrease	1,505,047	303,400
Accounts receivable trade	(15,914)	3,158
Inventory	108,127	100,178
Prepaid expenses	(9,455)	50,253
Due from Pulse Veterinary Technologies, LLC	57,693	(167,990)
Other assets	55	17,756
Assets held for sale	(1,316)	
Changes in liabilities increase/(decrease)		
Accounts payable	1,041,160	258,131
Payroll and related	449,371	(308,627)
Accrued expenses	(269,960)	(97,498)
NET CASH USED BY CONTINUING OPERATIONS	(4,133,549)	(5,205,366)
NET CASH PROVIDED BY DISCONTINUED OPERATIONS		708,237
NET CASH USED BY OPERATING ACTIVITIES	(4,133,549)	(4,497,129)
CASH FLOWS FROM INVESTING ACTIVITIES		
Continuing operations Proceeds from sale of property and equipment Purchase of property and equipment	7,000	9,142 (21,233)
NET CASH PROVIDED (USED) BY CONTINUING OPERATIONS NET CASH PROVIDED BY DISCONTINUED OPERATIONS	7,000	(12,091) 3,601,772
NET CASH PROVIDED BY INVESTING ACTIVITIES	7,000	3,589,681

# CASH FLOWS FROM FINANCING ACTIVITIES

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Continuing operations				
Proceeds from promissory notes		2,450,000		
Proceeds from sale of stock		300,000		1,819,844
Proceeds from notes payable, related parties				2,125,000
Repurchase of stock				(180,000)
Payment of development period liabilities				(69,915)
NET CASH PROVIDED BY FINANCING ACTIVITIES		2,750,000		3,694,929
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS		(16,681)		(33,671)
NET DIGDE LOE (DEGDE LOE) DI GLOVI LID GLOVI				
NET INCREASE (DECREASE) IN CASH AND CASH		(4.000.000)		2 = 2 2 2 2
EQUIVALENTS		(1,393,230)		2,753,810
CACILAND CACILEOLINALENTS DECIMAINS OF DEDICE		1 706 260		5.42.626
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		1,786,369		543,626
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	393,139	\$	2 207 426
CASH AND CASH EQUIVALENTS, END OF PERIOD	Ф	393,139	Ф	3,297,436

See accompanying notes to unaudited condensed consolidated financial statements.

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2010

#### 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 non-invasive, 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.

## 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, 2010 and for the three and nine months ended September 30, 2010 and 2009 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 period ended September 30, 2010 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2010. The condensed consolidated balance sheet at December 31, 2009 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, 2009, filed on March 31, 2010. Please refer also to Note 6 of 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 \$8,385,096 and \$3,450,462 for the nine months ended September 30, 2010 and 2009, respectively. The Company incurred a net loss from continuing operations of \$8,385,096 and \$6,520,796 for the nine months ended September 30, 2010 and 2009, respectively. The Company had a working capital deficiency of \$9,650,462 at September 30, 2010. These operating losses and working capital deficiency 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, promissory notes 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. The Company is economically dependent upon future financing to fund ongoing operations. See Liquidity and Capital Resources elsewhere in this report.

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 4. Common stock

On September 30, 2010, in conjunction with an offering of securities (the Offering ) of the Company pursuant to an exemption from registration under the Securities Act of 1933, as amended (the Act ), the Company issued 150,000 Units to certain accredited investors, as that term is defined in the Securities and Exchange Commission s (the SEC ) Rule 501 under the Act, for an aggregate total purchase price of \$300,000. The Offering was conducted pursuant to the exemption from registration provided by Rule 506 under the Act. Each Unit in the Offering consists of: (i) one share of common stock, par value \$0.001 per share (the 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 expires on December 31, 2010, to purchase the same number of Units as granted pursuant to this transaction, at the purchase price of \$2.00 per Unit.

# 5. Reverse Merger Transaction

On September 25, 2009, the Company (formerly named Rub Music Enterprises, Inc.) and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of the Company (the Merger Sub ) entered into a reverse merger agreement (the Merger Agreement ) with SANUWAVE, Inc. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, Inc., with SANUWAVE, Inc. as the surviving entity (the Merger ). In connection with the Merger, the Company acquired 100% of the outstanding capital stock of SANUWAVE, Inc. and the stockholders of SANUWAVE, Inc. received 11,009,657 shares of the Company s common stock, Class A warrants to purchase 1,106,627 shares of the Company s common stock at \$4.00 per share, and Class B warrants to purchase an additional 1,106,627 shares of the Company s common stock at \$8.00 per share. In addition, in connection with the Merger, certain stockholders of the Company agreed to cancel all of their shares of common stock of the Company, except for 1,500,000 shares of common stock, for an aggregate price of \$180,000 (the Share Repurchase ). At the time of the Merger, the Company had 1,500,000 Class C warrants outstanding to purchase the Company s common stock at \$4.00 per share.

As a result of the Merger and the Share Repurchase, the stockholders of SANUWAVE, Inc. controlled approximately 88% of the Company s outstanding common stock, holding 11,009,657 of the 12,509,657 outstanding shares, and SANUWAVE, Inc. was considered the accounting acquirer in this Merger. The Company was a shell company as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act ) immediately prior to the Merger. As a result of the Merger, the Company s operations are now focused in global medical technology and the Company is no longer a shell company.

# 6. Recently Issued Accounting Standards

In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-06, *Fair Value Measurements and Disclosures Topic 855* (ASU 2010-06). ASU 2010-06 provides amendments to ASC 820-10, *Fair Value Measurements* (ASC 820-10). ASC 820-10 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 three categories (level 1, level 2 or level 3). ASU 2010-06 provides amendments to ASC 820-10 to require new disclosures for transfers in and out of levels 1 and 2, as well as a reconciliation of activity within level 3. Furthermore, ASU 2010-06 provides amendments that clarify existing disclosures regarding levels of disaggregation and inputs and valuation techniques. The new disclosures and clarifications of existing disclosures required by ASU 2010-06 are effective for interim and annual reporting periods beginning after December 31, 2009 (except for disclosures in the reconciliation of activity within level 3, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years). The Company adopted ASU 2010-06 as of January 1, 2010, and the adoption did not have a material impact on the Company s condensed consolidated financial statements.

# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### **6. Recently Issued Accounting Standards (continued)**

In February 2010, the FASB issued ASU 2010-09, Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements (ASU 2010-09), to amend ASC 855, Subsequent Events (ASC 855). ASC 855, which was originally issued by the FASB in May 2009 (as SFAS No. 165, Subsequent Events), provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. ASC 855 distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. As a result of ASU 2010-09, companies are not required to disclose the date through which management evaluated subsequent events in the financial statements, either in originally issued financial statements or reissued financial statements. ASC 855 was effective for interim and annual periods ending after September 15, 2009, and ASU 2010-09 was effective immediately. The Company has evaluated subsequent events in accordance with ASU 2010-09, and the evaluation did not have a material impact on the Company s condensed consolidated financial statements.

### 7. Discontinued operations

On October 31, 2008, the Company discontinued its Ossatron<sup>®</sup> mobile service business.

On June 3, 2009, the Company sold its veterinary business to Pulse Veterinary Technologies, LLC ( Pulse Vet ) for a total cash consideration of \$3,500,000. As a result of the sale, the Company recorded a gain, before income taxes, of \$2,463,283.

Accordingly, the Company s condensed consolidated financial statements have been prepared with the net assets, results of operations, and cash flows of these businesses displayed separately as discontinued operations. The Ossatron devices and related parts inventory were subsequently reclassified, on October 1, 2009, to assets held for sale (see Note 8 Assets held for sale).

The operating results of the discontinued operations are summarized as follows:

	Three Months Ended September 30, 2010	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2010	E Septe	Months Ended Ember 30, 2009
Revenue Cost of revenues	\$	\$	\$	\$	1,458,107 372,547
Gross profit					1,085,560
Operating expenses					506,790
Operating income					578,770
Other income					2,536
Income from discontinued operations before income taxes Income tax expense					581,306
	\$	\$	\$	\$	581,306

Income from discontinued operations, net of income tax

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 7. Discontinued operations (continued)

The Company s assets (liabilities) related to discontinued operations were as follows:

	September 30, 2010			December 31, 2009		
Accrued expenses	\$	(655,061)	\$	(655,061)		
Net assets (liabilities) of discontinued operations	\$	(655,061)	\$	(655,061)		

#### 8. Assets held for sale

On October 31, 2008, the Company discontinued its Ossatron mobile service business and accordingly displayed the related assets of this business as discontinued operations (Note 7). In accordance with FASB ASC 205-20, *Presentation of Financial Statements Discontinued Operations*, a quarterly review of the discontinued assets was performed to determine if they should continue to be recorded as discontinued operations. As of October 1, 2009, management determined that the Ossatron device fixed assets and related parts inventory should be reclassified to continuing operations, and depreciation on the Ossatron device fixed assets was restarted at October 1, 2009. Assets held for sale consist of the following:

	Se	ptember 30, 2010	De	ecember 31, 2009
Ossatron devices Less accumulated depreciation	\$	4,837,165 (4,550,791)	\$	4,837,165 (4,082,474)
Net property and equipment		286,374		754,691
Inventory Ossatron device parts		226,081		210,169
Provision for losses and obsolescence		(56,500)		(41,904)
Net inventory		169,581		168,265
Total assets held for sale	\$	455,955	\$	922,956

The aggregate depreciation charged to operations was \$139,312 for the three months ended September 30, 2010, and \$468,317 for the nine months ended September 30, 2010. There was no depreciation expense charged to operations for the three and nine months ended September 30, 2009.

# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

## 9. Inventory

Inventory consists of the following:

,										
	Sep	September 30, 2010		•		•		•		cember 31, 2009
Inventory finished goods Inventory parts	\$	565,239 77,023	\$	667,998 108,068						
Provision for losses and obsolescence		642,262 (157,800)		776,066 (183,477)						
Net inventory	\$	484,462	\$	592,589						
10. Property and equipment Property and equipment consists of the following:										
	Sep	tember 30, 2010	Dec	cember 31, 2009						

	Sej	September 30, 2010		December 31, 2009		
Machines and equipment	\$	199,520	\$	199,520		
Office and computer equipment		296,120		311,791		
Leasehold improvements		67,421		67,421		
Furniture and fixtures		24,613		24,613		
Vehicles		22,531		38,897		
Software		40,233		40,233		
Other assets		4,585		4,585		
Total		655,023		687,060		
Less accumulated depreciation		(633,567)		(598,354)		
Net property and equipment	\$	21,456	\$	88,706		

The aggregate depreciation charged to operations was \$15,886 and \$46,636 for the three months ended September 30, 2010 and 2009, respectively, and \$66,815 and \$150,482 for the nine months ended September 30, 2010 and 2009, respectively.

# 11. Intangible assets

Intangible assets consist of the following:

	Se	ptember 30, 2010	De	ecember 31, 2009
Patents, at cost Less accumulated amortization	\$	3,502,135 (1,584,908)	\$	3,502,135 (1,354,840)
Net intangible assets	\$	1,917,227	\$	2,147,295

The aggregate amortization charged to operations was \$76,689 and \$76,689 for the three months ended September 30, 2010 and 2009, respectively, and \$230,068 and \$230,067 for the nine months ended September 30, 2010 and 2009, respectively.

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 12. Accrued expenses

Accrued expenses consist of the following:

	Sep	tember 30, 2010	Dec	cember 31, 2009
Accrued legal professional fees Accrued clinical site payments Accrued audit and tax preparation Accrued other	\$	77,577 81,141 94,102 106,249	\$	249,418 192,023 77,771 109,817
	\$	359,069	\$	629,029

#### 13. Income taxes

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

At September 30, 2010, the Company had federal net operating loss (NOL) carryforwards of \$32,826,987 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 on ASC 740, *Income Taxes* (formerly SFAS No. 109), the Company s management believes that there is not sufficient evidence at September 30, 2010, indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2010. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including loss 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 would further limit its ability to use its NOL carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because U.S. 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.

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

# 14. Promissory notes

The promissory notes consist of the following:

Promissory note, unsecured, bearing interest at 5%, issued to David N. Nemelka on March 1, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on June 1, 2010. The principal was not repaid at the due date and therefore, in accordance with the	Sept	tember 30, 2010
terms of the promissory note, the interest rate increased to 10% effective June 1, 2010. Accrued interest totaled \$9,346 at September 30, 2010.	\$	209,346
Promissory note, unsecured, bearing interest at 5%, issued to Kevin and Margaret Richardson on March 4, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on June 4, 2010. The principal was not repaid at the due date and therefore, in accordance with the terms of the promissory note, the interest rate increased to 10% effective June 4, 2010. Accrued interest totaled \$9,115 at September 30, 2010.		209,115
Promissory note, unsecured, bearing interest at 5%, issued to David N. Nemelka on March 31, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on June 30, 2010. The principal was not repaid at the due date and therefore, in accordance with the terms of the promissory note, the interest rate increased to 10% effective June 30, 2010. Accrued interest totaled \$11,423 at September 30, 2010.		311,423
Promissory note, unsecured, bearing interest at 5%, issued to Kevin and Margaret Richardson on March 31, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on June 30, 2010. The principal was not repaid at the due date and therefore, in accordance with the terms of the promissory note, the interest rate increased to 10% effective June 30, 2010. Accrued interest totaled \$11,423 at September 30, 2010.		311,423

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

# 14. Promissory notes (continued)

	Sej	ptember 30, 2010
Promissory note, unsecured, bearing interest at 5% issued to Kevin and Margaret Richardson on May 12, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on August 12, 2010. The accrued interest and principal was not paid on the due date and therefore, in accordance with the terms of the promissory note, the interest rate increased to 10% effective August 12, 2010. Accrued interest totaled \$7,830 at September 30, 2010.		307,830
Promissory note, unsecured, bearing interest at 5% issued to Durk V. Irwin on June 4, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on September 4, 2010. The accrued interest and principal was not paid on the due date and therefore, in accordance with the terms of the promissory note, the interest rate increased to 10% effective September 4, 2010. Accrued interest totaled \$1,987 at September 30, 2010		101,987
Promissory note, unsecured, bearing interest at 5% issued to Todd R. Pedersen on June 4, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal was due on September 4, 2010. The accrued interest and principal was not paid on the due date and therefore, in accordance with the terms of the promissory note, the interest rate increased to 10% effective September 4, 2010. Accrued interest totaled \$1,987 at September 30, 2010.		101,987
Promissory note, unsecured, bearing interest at 5% issued to Kevin and Margaret Richardson on July 13, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal is due October 12, 2010. Accrued interest totaled \$5,366 at September 30, 2010.		505,366
Promissory note, unsecured, bearing interest at 5% issued to Kevin and Margaret Richardson on August 12, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal is due November 12, 2010. Accrued interest totaled \$1,335 at September 30, 2010.		201,335
Promissory note, unsecured, bearing interest at 5% issued to Kevin and Margaret Richardson on August 30, 2010. Interest is accrued and added to the principal balance. All accrued interest and principal is due November 30, 2010. Accrued interest totaled \$1,076 at September 30, 2010.		251,076
Total promissory notes	\$	2,510,888

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 14. Promissory notes (continued)

Subsequent to quarter end, on October 12, 2010, the outstanding principal and interest on the promissory notes was exchanged into Units equal to (i) the unpaid principal and interest on each such note, divided by (ii) 2 (see Note 21 Subsequent events). 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. Each Unit consists of: (i) one share of Common Stock; (ii) a two-year Class D Warrant to purchase one share of Common Stock, at an exercise price of \$2.00; and (iii) an Option, which expires on December 31, 2010, to purchase the same number of Units as the holder received pursuant to this exchange, at the purchase price of \$2.00 per Unit.

Kevin Richardson is a member of the Board of Directors of the Company and is the managing partner of Prides Capital LLC, a shareholder of the Company. David N. Nemelka, Durk V. Irwin, and Todd R. Pedersen are shareholders of the Company.

Interest expense on promissory notes totaled \$42,460 for the three months ended September 30, 2010 and \$60,888 for the nine months ended September 30, 2010.

There were no promissory notes outstanding during fiscal year 2009.

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 15. Notes payable, related parties

The notes payable, related parties consist of the following:

	Se	eptember 30, 2010	De	ecember 31, 2009
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 is 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. Unpaid accrued interest not payable until August 1, 2015 totaled \$1,372,744 and \$1,215,253 at September 30, 2010 and December 31, 2009, respectively.	\$	5,372,744	\$	5,215,253
Notes payable, unsecured, bearing interest at 15% to Prides Capital Fund I, LP and NightWatch Capital Partners II, LP, shareholders of the Company. Quarterly interest through September 30, 2010 is accrued and added to the principal balance. Interest is paid quarterly in arrears if elected by the holder. As of September 30, 2010, the holder has not elected to have interest paid. All unpaid accrued interest and principal is due September 30, 2011. Accrued interest totaled \$907,182 and \$472,728 at September 30, 2010 and December 31, 2009, respectively. At the option of the holder, all or any portion of the unpaid principal can be converted into common stock with a conversion				
price of \$2.92 per share.		4,107,182		3,672,728
Total Less current portion		9,479,926 (4,107,182)		8,887,981
Non-current portion	\$	5,372,744	\$	8,887,981

Interest expense on notes payable, related parties totaled \$232,112 and \$197,477 for the three months ended September 30, 2010 and 2009, respectively, and \$673,809 and \$528,119 for the nine months ended September 30, 2010 and 2009, respectively.

## 16. 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 NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 16. Earnings (Loss) Per Share (continued)

As a result of the net loss from continuing operations for the nine months ended September 30, 2010 and 2009, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net income (loss) per share. The anti-dilutive common shares totaled 1,580,353 shares and 1,185,813 shares for the three months ended September 30, 2010 and 2009, respectively, and 1,669,885 shares and 955,867 shares for the nine months ended September 30, 2010 and 2009, respectively.

## 17. Commitments and Contingencies

The Company leases office and warehouse space. Rent expense was \$83,908 and \$120,564 for the three months ended September 30, 2010 and 2009, respectively, and \$254,190 and \$368,602 for the nine months ended September 30, 2010 and 2009, respectively.

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 consolidated financial position or results of operations of the Company.

#### 18. 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 \$18,310 and \$14,503 to the plan for the three months ended September 30, 2010 and 2009, respectively, and \$53,094 and \$48,863 to the plan for the nine months ended September 30, 2010 and 2009, respectively.

### 19. Stock-based compensation

During 2006, SANUWAVE, Inc. approved the 2006 Stock Incentive Plan and certain Nonstatutory Stock Option Agreements with key employees. The Nonstatutory Stock Option Agreements have terms substantially the same as the 2006 Stock Incentive Plan. 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. Options granted may include nonstatutory options as well as qualified incentive stock options. 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. The stock options granted under the Amended Plan are nonstatutory options which vest equally over a period of up to four years, and have a ten year term. The options were 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.

On January 29, 2010, the Company granted 107,500 options to employees and directors at an exercise price of \$4.05 per share. Using the Black-Scholes option pricing model, management has determined that the options granted in 2010 had a weighted average fair value per share of \$2.06 resulting in total compensation cost of \$455,625. Compensation cost will be recognized over the applicable service period.

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 19. Stock-based compensation (continued)

The Company recognized as compensation cost for all outstanding stock options, restricted stock and warrants granted to employees and directors, \$451,947 and \$318,008 for the three months ended September 30, 2010 and 2009, respectively, and \$1,389,647 and \$585,400 for the nine months ended September 30, 2010 and 2009, respectively. The assumptions used are as follows:

Nine Months Ended September 30, 2010

Expected life in years

Risk free interest rate

Weighted average volatility

Expected dividend yield (1)

6.0

2.41%
65.00%

## (1) The Company

has not paid

dividends on its

common stock

and does not

expect to pay

dividends on its

common stock

in the near

future.

A summary of option activity as of September 30, 2010 and December 31, 2009, and the changes during the three and nine months ended September 30, 2010, is presented as follows:

			ighted
			rerage
			ercise
	Options	P	rice
Outstanding as of December 31, 2009	1,979,546	\$	3.70
Granted	107,500	\$	4.05
Exercised		\$	
Forfeited or expired	(2,500)	\$	2.92
Outstanding as of March 31, 2010	2,084,546	\$	3.72
Granted		\$	
Exercised		\$	
Forfeited or expired	(3,750)	\$	3.30
Outstanding as of June 30, 2010	2,080,796	\$	3.72
Granted		\$	
Exercised		\$	
Forfeited or expired		\$	

Outstanding as of September 30, 2010		2,080,796	\$ 3.72
Exercisable		1,871,736	\$ 3.68
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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

## 19. Stock-based compensation (continued)

The weighted average remaining contractual term for outstanding and exercisable stock options is 5.6 years as of September 30, 2010 and 6.3 years as of December 31, 2009.

A summary of the Company s nonvested options as of September 30, 2010 and December 31, 2009, and changes during the three and nine months ended September 30, 2010, is presented as follows:

		Weighted Average Grant-Date
	Options	Fair Value
Nonvested as of December 31, 2009	273,471	\$ 997,589
Granted	107,500	455,625
Vested	(20,911)	(61,060)
Forfeited or expired	(2,500)	(7,300)
Nonvested as of March 31, 2010	357,560	1,384,854
Granted		
Vested	(131,000)	(453,422)
Forfeited or expired	(3,750)	(12,363)
Nonvested as of June 30, 2010	222,810	919,069
Granted		
Vested	(13,750)	(40,150)
Forfeited or expired		
Nonvested as of September 30, 2010	209,060	\$ 878,919

Subsequent to quarter end, on November 1, 2010, the Company granted 912,000 options to employees and directors at an exercise price of \$2.00 per share.

A summary of the Company s restricted stock as of September 30, 2010 and December 31, 2009, and changes during the nine months ended September 30, 2010, is presented as follows:

Outstanding as of December 31, 2009 Granted Vested Forfeited or expired	Restricted Stock 403,030
Outstanding as of September 30, 2010	403,030

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# SANUWAVE HEALTH, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) September 30, 2010

#### 20. Warrants

As of September 30, 2010, the Company had (1) Class A warrants to purchase up to 1,106,627 shares of common stock outstanding, (2) Class B warrants to purchase up to 1,106,627 shares of common stock outstanding, and (3) Class D warrants to purchase up to 150,000 shares of common stock outstanding. The Class A warrants and Class B warrants expire on September 25, 2014 and the Class D warrants expire on September 30, 2012. The Class A warrants have an exercise price of \$4.00 per share, the Class B warrants have an exercise price of \$8.00 per share, and the Class D warrants have an exercise price of \$2.00 per share.

The exercise price and the number of shares covered by the warrants will be adjusted if the Company has a stock split, if there is a recapitalization of the Company s common stock, or if the Company consolidates with or merges into another corporation.

The Company s Class C warrants were cancelled on July 23, 2010.

#### 21. Subsequent events

On October 1, 2010, in conjunction with the Offering discussed in Note 4 Common stock, the Company issued 250,000 Units to an accredited investor for \$500,000.

Effective October 12, 2010, the Company amended the terms of ten outstanding promissory notes with an initial aggregate issuance amount of \$2,450,000 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 consists of: (i) one share of common stock, par value \$0.001 per share (the 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 expires on December 31, 2010, 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. Kevin A. Richardson II, who is the chairman of the board of directors of the Company, is one of the noteholders who exchanged notes in the transaction.

On November 1, 2010, the Company s board of directors approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010, which, among other provisions, increased the shares of common stock reserved for grant to 5,000,000. On November 1, 2010, the Company granted 912,000 options to employees and directors at an exercise price of \$2.00 per share.

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# 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, 2009 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 31, 2010.

#### Overview

We are an emerging global regenerative medicine company focused on the development and commercialization of non-invasive, 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 FDA Class III PMA approved Ossatron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our Ossatron and Evotron®, and newly introduced orthoPACE devices in Europe. Our lead product candidate for the global wound care market, dermaPACE , has received the European Conformity Marking ( CE Mark ) allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

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 procedures for removing plaque due to atherosclerosis and improving heart muscle performance.

#### **Recent Developments**

We have completed enrolling patients and the patient follow-up phase for our first IDE wound care clinical study focused on the healing of diabetic foot ulcers utilizing our lead product candidate, dermaPACE. 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. A total of 206 patients have 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 reepithelialized without drainage or dressing requirements confirmed at two consecutive study visits. We completed the patient follow-up phase of this trial in September 2010. We expect to report top-line results in the fourth quarter of 2010, to file our Premarket Approval Application (PMA) with the FDA no later than the first quarter of 2011, and, pending a favorable response from the FDA, to launch dermaPACE in the United States in 2011.

We launched in Europe the orthoPACE device intended for use in orthopedic, trauma and sports medicine indications following CE Mark approval in June 2010. The device features a new, unique applicator that is less painful for some indications and may reduce or completely eliminate anesthesia for some patients. In the orthopedic setting, the orthoPACE will initially be used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs. The first shipments of the new orthoPACE device were made in the third quarter of 2010.

We believe our experience from preclinical research and the clinical use of our predecessor devices in Europe and Asia, as well as our Ossatron device in the United States for the last nine years, demonstrates the safety, clinical utility and efficacy of our product candidates. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications, as well as toward the development of next generation devices utilizing our PACE technology to maximize healing response and intervention.

We believe that these studies suggest that our platform technology will be effective in our target applications. If successful, we expect these clinical studies should lead to regulatory approval of our regenerative product candidates in the United States, Europe and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and non-invasive treatment options in wound healing, orthopedic/spine injuries, plastic/cosmetic uses and cardiac procedures, improving the quality of life for millions of patients suffering from injuries or deterioration of tissue, bones and vascular structures.

#### **Financial Overview**

Since our inception in 2005, we have funded our operations from the sale of capital stock, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009, and product sales. At September 30, 2010, the balance of cash and cash equivalents totaled \$0.4 million. Subsequent to quarter end, we received \$0.5 million on October 1, 2010 from the sale of Units described in footnote 21 to the accompanying condensed consolidated financial statements.

We continue to incur research and development expenses for clinical trials and the development of products for additional indications. We expect that research and development expenses will continue to increase 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.

Since our inception, we have incurred losses from operations each year. As of September 30, 2010, we had an accumulated deficit of \$47 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 and clinical trials, and as we prepare for a future sales network to represent 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;

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 as businesses and individuals suffer from the current economic recession.

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 in our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 31, 2010.

#### **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, 2009, filed with the SEC on March 31, 2010, 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 and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

### Revenue Recognition

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

#### 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.

# **Stock-based Compensation**

During 2006, SANUWAVE, Inc. s board of directors approved the adoption of the 2006 Stock Incentive Plan which was assumed by the Company following the Merger. 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 determined by the Company s board of directors, at the time the option is granted, taking into account the fair value of the common stock on the date of grant. The maximum term of any option granted pursuant to the Amended Plan is ten years from the

date of grant.

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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 granted are estimated to be outstanding and are derived from the contractual terms of the options granted. We amortize the fair value of each option over each option s vesting period.

#### **Income Taxes**

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109, Accounting for Income Taxes). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax 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 carry-forwards, 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, 2010 and 2009 (Unaudited) Revenues and Cost of Revenues

Revenues for the three months ended September 30, 2010 were \$278,212, compared to \$134,771 for the same period in 2009, an increase of \$143,441, or 106%. Revenues resulted primarily from sales of devices and applicators in Europe. Revenues increased for the three months ended September 30, 2010 compared to 2009 primarily as a result of the European launch of our orthoPACE device in June 2010.

Cost of revenues for the three months ended September 30, 2010 was \$109,801, compared to \$30,753 for the same period in 2009. Gross profit as a percentage of revenues was 61% for the three months ended September 30, 2010, as compared to 77% for the same period in 2009. The decrease in gross profit in 2010 was due to lower margin on orthoPACE device sales sold to distributors for use as demonstration devices and higher freight costs in 2010 associated with the Company assembling its products in the United States for sale in Europe instead of assembling in Europe as it did in 2009.

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#### Research and Development Expenses

Research and development expenses for the three months ended September 30, 2010 were \$1,000,265, compared to \$1,063,875 for the same period in 2009, a decrease of \$63,610, or 6%. 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 costs decreased slightly for the three months ended September 30, 2010, as compared to the same period in 2009, due to lower clinical site costs.

We expect that research and development expenses will increase as a result of next generation technology development, the ongoing clinical trial of dermaPACE for diabetic foot ulcers in the United States and other new product candidates, as well as continuing expenses associated with pre-clinical studies and regulatory filings. *General and Administrative Expenses* 

General and administrative expenses for the three months ended September 30, 2010 were \$1,393,826, compared to \$1,530,281 for the same period in 2009, a decrease of \$136,455, or 9%. General and administrative expenses include the non-cash compensation costs for stock compensation of \$451,947 for the three months ended September 30, 2010, compared to \$318,008 for the same period in 2009, due to new grants of options and restricted stock to employees and directors of the Company in September 2009 and January 2010.

Excluding the non-cash compensation costs for stock compensation, general and administrative expenses were \$941,879 for the three months ended September 30, 2010, as compared to \$1,212,273 for the same period in 2009, a decrease of \$270,394 or 22%. The decrease was due to additional one-time accounting and legal fees incurred in September 2009 related to the reverse merger transaction.

We expect that general and administrative expenses will increase as we expand our operations and other administrative activities related to our efforts to bring our products to commercialization.

## Depreciation

Depreciation for the three months ended September 30, 2010 was \$155,198, compared to \$46,636 for the same period in 2009, an increase of \$108,562, or 233%. On October 31, 2008, the Company discontinued its Ossatron mobile service business and accordingly displayed the related assets of this business as discontinued operations. As of October 1, 2009, management determined that the Ossatron device fixed assets and related parts inventory should be reclassified to continuing operations and depreciation on the Ossatron device fixed assets was restarted at October 1, 2009. The depreciation expense related to these assets was \$139,312 for the three months ended September 30, 2010. There was no depreciation expense recorded for these assets for the three months ended September 30, 2009. *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, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. This was amended on July 28, 2010 to extend this agreement until April 30, 2012. The income for these transitional services was \$90,000 and \$102,500 for the three months ended September 30, 2010 and 2009, respectively. The decrease is due to Pulse Vet discontinuing the accounting services provided by the Company effective July 31, 2009.

Interest expense, net, for the three months ended September 30, 2010 was \$274,247, compared to \$188,279 for the same period in 2009, an increase of \$85,968, or 46%. The increase was due to interest at 15% per annum on additional notes payable, related parties, issued during 2009, and interest at 5% to 10% per annum on promissory notes issued during 2010.

### Provision for Income Taxes

At September 30, 2010, we had Federal net operating loss carryforwards of approximately \$32.8 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.

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#### Net Loss

Net loss for the three months ended September 30, 2010 was \$2,663,191, or (\$0.21) per basic and diluted share, compared to a net loss of \$2,700,000, or (\$0.23) per basic and diluted share, for the three months ended September 30, 2009. The loss from continuing operations was \$2,663,191, or (\$0.21) per basic and diluted share, for the three months ended September 30, 2010, compared to a loss of \$2,696,755, or (\$0.23) per basic and diluted share, for the three months ended September 30, 2009. We anticipate that our operating losses will continue over the next few years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products.

## Results of Operations for the Nine Months ended September 30, 2010 and 2009 (Unaudited)

## Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2010 were \$538,540, compared to \$538,818 for the same period in 2009, a decrease of \$278. These revenues resulted primarily from sales of devices and applicators in Europe of our legacy Evotron device for orthopedic conditions and our new orthoPACE device for orthopedic conditions introduced in June 2010.

Cost of revenues for the nine months ended September 30, 2010 was \$198,381, compared to \$129,416 for the same period in 2009. Gross profit as a percentage of revenues was 63% for the nine months ended September 30, 2010, as compared to 76% for the same period in 2009. The decrease in gross profit in 2010 was due to lower margin on orthoPACE device sales sold to distributors for use as demonstration devices and higher freight costs in 2010 associated with the Company assembling its products in the United States for sale in Europe instead of assembling in Europe as it did in 2009.

#### Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2010 were \$2,981,890, compared to \$2,686,160 for the same period in 2009, an increase of \$295,730, or 11%. 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 costs increased in 2010 as compared to the same period in 2009 due to higher costs of the ongoing clinical trial of dermaPACE for diabetic foot ulcers in the United States as enrollment ended during the first quarter of 2010 and new consultants were engaged to assist in the patient follow-up phase of the clinical trial.

#### General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2010 were \$4,490,586, compared to \$3,433,448 for the same period in 2009, an increase of \$1,057,138, or 31%. General and administrative expenses include the non-cash compensation costs for stock compensation of \$1,389,647 for the nine months ended September 30, 2010, compared to \$585,400 for the same period in 2009, due to new grants of options and restricted stock to employees and directors of the Company in September 2009 and January 2010.

Excluding the non-cash compensation costs for stock compensation, general and administrative expenses were \$3,100,939, for the nine months ended September 30, 2010, as compared to \$2,848,048 for the same period in 2009, an increase of \$252,891 or 9%. The increase is primarily due to higher bonus expense accrued in 2010 as compared to 2009 offset by the additional accounting and legal costs incurred in 2009 for the September 2009 reverse merger transaction.

#### Depreciation

Depreciation for the nine months ended September 30, 2010 was \$535,132, compared to \$150,482 for the same period in 2009, an increase of \$384,650, or 256%. On October 31, 2008, the Company discontinued its Ossatron mobile service business and accordingly displayed the related assets of this business as discontinued operations. As of October 1, 2009, management determined that the Ossatron device fixed assets and related parts inventory should be reclassified to continuing operations and depreciation on the Ossatron device fixed assets was restarted at October 1, 2009. The depreciation expense related to these assets was \$468,317 for the nine months ended September 30, 2010.

There was no depreciation expense recorded for these assets for the nine months ended September 30, 2009.

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#### 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, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. This was amended on July 28, 2010 to extend this agreement until April 30, 2012. The income for these transitional services for the nine months ended September 30, 2010 was \$270,125, compared to \$136,250 for the same period in 2009, an increase of \$133,875, or 98%, as a result of the services not beginning until June 2009.

Interest expense, net, for the nine months ended September 30, 2010 was \$731,771, compared to \$517,354 for the same period in 2009, an increase of \$214,417, or 41%. The increase was due to interest at 15% per annum on additional notes payable, related parties, totaling \$2,125,000 issued during the nine months ended September 30, 2009, and interest at 5% to 10% per annum on promissory notes totaling \$2,450,000 issued during the nine months ended September 30, 2010.

## Provision for Income Taxes

At September 30, 2010, we had Federal net operating loss carryforwards of approximately \$32.8 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.

# Income from Discontinued Operations

On June 3, 2009, we sold our veterinary division for \$3,500,000 in cash to Pulse Vet and recognized a gain, net of taxes, of \$2,489,028. The income from discontinued operations was \$581,306 for the nine months ended September 30, 2009.

#### Net Loss

Net loss for the nine months ended September 30, 2010 was \$8,385,096, or (\$0.67) per basic and diluted share, compared to net loss of \$3,450,462, or (\$0.30) per basic and diluted share, for the nine months ended September 30, 2009. The net loss for the nine months ended September 30, 2009, included a gain, net of taxes, of \$2,489,028 attributable to the sale of our veterinary division. The loss from continuing operations was \$8,385,096, or (\$0.67) per basic and diluted share, for the nine months ended September 30, 2010, compared to a loss of \$6,520,796, or (\$0.56) per basic and diluted share, for the nine months ended September 30, 2009. We anticipate that our operating losses will continue over the next few years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products.

#### **Liquidity and Capital Resources**

We incurred a net loss of \$8,385,096 for the nine months ended September 30, 2010, and a loss from continuing operations of \$6,520,796 for the nine months ended September 30, 2009. We had a working capital deficiency of \$9,650,462 at September 30, 2010. These operating losses and working capital deficiency create an 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, promissory notes, 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. We are economically dependent upon future capital contributions or financing to fund ongoing operations.

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For the nine months ended September 30, 2010, the Company issued ten promissory notes totaling \$2,450,000. Subsequent to quarter end, 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 of 1933, as amended (the 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 consists of: (i) one share of common stock, par value \$0.001 per share (the 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 expires on December 31, 2010, 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. Kevin A. Richardson II, who is the chairman of the board of directors of the Company, is one of the noteholders who exchanged notes in the Offering.

On September 30, 2010, in conjunction with the Offering, the Company issued 150,000 Units to certain accredited investors, as that term is defined in the Securities and Exchange Commission s (the SEC) Rule 501 under the Act, for an aggregate total purchase price of \$300,000. Subsequent to quarter end, on October 1, 2010, in conjunction with the Offering, the Company issued 250,000 Units to an accredited investor for \$500,000. Each Unit was sold to the new investors at a purchase price of \$2.00 per Unit.

At September 30, 2010, we had \$393,139 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. Clinical study costs are comprised of payments for work performed by contract research organizations, universities and hospitals. 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 resources. 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. 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. For the nine months ended September 30, 2010, net cash used by continuing operations for operating activities was \$4,133,549, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by continuing operations for financing activities for the nine months ended September 30, 2010 was \$2,750,000, which consisted of the proceeds from 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.

For the nine months ended September 30, 2009, net cash used by continuing operations for operating activities was \$5,205,366, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by continuing operations for financing activities for the nine months ended September 30, 2009 was \$3,694,929, which consisted of the proceeds from the issuance of notes payable to related parties of \$2,125,000 and the sale of common stock to accredited investors of \$1,819,844 offset by the repurchase of common stock of \$180,000 and payment of development period liabilities of \$69,915 prior to the reverse merger transaction. Net cash provided by discontinued operations for operating activities was \$708,237 for the nine months ended September 30, 2009. Net cash provided by discontinued operations for investing activities was \$3,601,772 for the nine months ended September 30, 2009 from the sale of the veterinarian division. Cash and cash equivalents increased by \$2,753,810 for the nine months ended September 30, 2009.

## **Segment Information**

We have determined that we are principally engaged in one operating segment. Our product candidates are primarily used for the repair and regeneration of tissue, musculoskeletal and vascular structures in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions.

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#### **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 on our most recent Annual Report on Form 10-K and subsequent quarterly reports on Form 10-Q. The following material contractual obligations were entered into by us during the quarter ended September 30, 2010: On July 13, 2010, we issued a promissory note to Kevin and Margaret Richardson in the amount of \$500,000. The promissory note bears interest at 5% annually. All accrued interest and principal was due October 13, 2010. Accrued interest on the promissory note totaled \$5,366 at September 30, 2010. Subsequent to quarter end, on October 12, 2010, the note was exchanged into Units as described in the Liquidity and Capital Resources section above. On August 12, 2010, we issued a promissory note to Kevin and Margaret Richardson in the amount of \$200,000. The promissory note bears interest at 5% annually. Accrued interest on the promissory note totaled \$1,335 at September 30, 2010. Subsequent to quarter end, on October 12, 2010, the note was exchanged into Units as described in the Liquidity and Capital Resources section above.

On August 30, 2010, we issued a promissory note to Kevin and Margaret Richardson in the amount of \$250,000. The promissory note bears interest at 5% annually. Accrued interest on the promissory note totaled \$1,077 at September 30, 2010. Subsequent to quarter end, on October 12, 2010, the note was exchanged into Units as described in the Liquidity and Capital Resources section above.

#### **Off-Balance Sheet Arrangements**

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

#### **Effects of Inflation**

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

**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 is 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 is 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 and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2010. 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, 2010.

#### **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 affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II OTHER INFORMATION

#### Item 1. LEGAL PROCEEDINGS

Other than legal proceedings described below and those relating to our intellectual property, there are no material pending legal proceedings to which we are a party or of which any of our properties are subject; nor are there material proceedings known to us to be contemplated by any governmental authority. We have several material pending legal proceedings relating to our patents. For information regarding these legal proceedings, please see the section entitled Intellectual Property Patents in our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 31, 2010.

HealthTronics, 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. The plaintiff is seeking greater than \$3 million. HealthTronics has been responsible for the defense of the lawsuit on behalf of the Company and believes the case is unfounded and is contesting the claims vigorously.

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

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# Item 6. EXHIBITS

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
4.1	Promissory Note, dated July 13, 2010, issued by SANUWAVE Health, Inc. to Kevin and Margaret Richardson. (Incorporated by reference to the Form 8-K filed with the SEC on July 16, 2010).
4.2	Promissory Note, dated August 12, 2010, issued by SANUWAVE Health, Inc. to Kevin and Margaret Richardson. (Incorporated by reference to the Form 8-K filed with the SEC on August 17, 2010).
4.3	Promissory Note, dated August 30, 2010, issued by SANUWAVE Health, Inc. to Kevin and Margaret Richardson. (Incorporated by reference to the Form 8-K filed with the SEC on September 1, 2010).
4.4	Form of Promissory Note Amendment. (Incorporated by reference to the Form 8-K filed with the SEC on October 14, 2010).
4.5	Form of Subscription Agreement. (Incorporated by reference to the Form 8-K filed with the SEC on October 14, 2010).
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.

\* Filed herewith

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#### **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 12, 2010

# SANUWAVE HEALTH, INC.

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

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