SANUWAVE Health, Inc.
Form 10-Q
November 12, 2015
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, 2015

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

For the transition period from _____ to

Commission File Number 000-52985

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

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

(Address of principal executive offices) (Zip Code)

(770) 419-7525

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

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

As of November 9, 2015, there were issued and outstanding 63,056,519 shares of the registrant’s common stock, $0.001 par value.

SANUWAVE Health, Inc.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of SANUWAVE Health, Inc. and its subsidiaries ("SANUWAVE" or the "Company") contains forward-looking statements. All statements in this Quarterly Report on Form 10-Q, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company's future financial results, clinical trial results, regulatory approvals, operating results, business strategies, projected costs, products, competitive positions, management's plans and objectives for future operations, and industry trends. These forward-looking statements are based on management's estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" and "co negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission (the "SEC"), 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, 2014, filed on March 3, 2015 and in the Company's Quarterly Reports on Form 10-Q. Other risks and uncertainties are and will be disclosed in the Company's prior and future SEC filings. These and many other factors could affect the Company's future financial condition and operating results and could cause actual results to differ materially from expectations based on forward-looking statements made in this document or elsewhere by the Company or on its behalf. The Company undertakes no obligation to revise or update any forward-looking statements. The following information should be read in conjunction with the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed on March 3, 2015.

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

PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	September 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$625,450	$3,547,071
Accounts receivable, net of allowance for doubtful accountsof $5,832 in 2015 and $15,018 in 2014	32,008	86,404
Inventory	291,354	271,871
Prepaid expenses	152,261	128,550
TOTAL CURRENT ASSETS	1,101,073	4,033,896
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4)	5,065	7,840
OTHER ASSETS	11,160	11,106
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 5)	383,445	613,513
TOTAL ASSETS	$1,500,743	$4,666,355
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$315,651	$231,840
Accrued expenses (Note 6)	400,488	369,456
Accrued employee compensation	200,807	2,226
Interest payable, related parties (Note 7)	100,123	81,864
Notes payable, related parties (Note 7)	-	5,372,743
Warrant liability (Note 11)	267,600	159,626
TOTAL CURRENT LIABILITIES	1,284,669	6,217,755
NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 7)	5,342,412	-
TOTAL LIABILITIES	6,627,081	6,217,755

COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001,6,175 authorized; 6,175 shares issued and 0 and 1,165 shares outstanding in 2015 and 2014, respectively (Note 10)	-	1
PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,825 shares authorized; no shares issued and outstanding (Note 10)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 63,056,519 and 60,726,519 issued and outstanding in 2015 and 2014, respectively (Note 9)	63,057	60,727
ADDITIONAL PAID-IN CAPITAL	86,728,528	86,584,472
ACCUMULATED DEFICIT	(91,891,615)	(88,184,123)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(26,308)	(12,477)
TOTAL STOCKHOLDERS' DEFICIT	(5,126,338)	(1,551,400)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,500,743	$4,666,355

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
REVENUES	$143,605	$227,492	$594,040	$610,705
COST OF REVENUES	38,752	68,077	173,349	149,813
GROSS PROFIT	104,853	159,415	420,691	460,892
OPERATING EXPENSES				
Research and development	569,134	708,304	1,660,546	2,486,801
General and administrative	778,679	780,115	1,981,541	2,774,828
Depreciation	926	3,827	2,775	13,312
Amortization	76,689	76,689	230,068	230,067
TOTAL OPERATING EXPENSES	1,425,428	1,568,935	3,874,930	5,505,008
OPERATING LOSS	(1,320,575)	(1,409,520)	(3,454,239)	(5,044,116)
OTHER INCOME (EXPENSE)				
Gain on sale of assets held for sale	100,000	-	100,000	-
Gain (loss) on warrant valuation adjustment (Note 12)	302,300	-	(70,985)	-
Interest expense, net	(105,830)	(79,955)	(266,810)	(700,085)
Loss on foreign currency exchange	(2,739)	(3,430)	(15,458)	(6,308)
TOTAL OTHER INCOME (EXPENSE)	293,731	(83,385)	(253,253)	(706,393)
NET LOSS	(1,026,844)	(1,492,905)	(3,707,492)	(5,750,509)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	(345)	(10,210)	(13,831)	(15,191)
TOTAL COMPREHENSIVE LOSS	$(1,027,189)	$(1,503,115)	$(3,721,323)	$(5,765,700)
LOSS PER SHARE:				
Net loss - basic and diluted	$(0.02)	$(0.03)	$(0.06)	$(0.12)
Weighted average shares outstanding - basic and diluted	63,056,519	50,706,519	63,014,763	46,258,912

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(3,707,492)	$(5,750,509)
Adjustments to reconcile loss from continuing operationsto net cash used by operating activities		
Amortization	230,068	230,067
Depreciation	2,775	13,312
Change in allowance for doubtful accounts	(9,186)	4,762
Stock-based compensation - employees, directors and advisors	146,385	91,788
Loss on warrant valuation adjustment	70,985	-
Amortization of debt discount	6,658	-
Gain on sale of property and equipment	(100,000)	
Stock issued for consulting services	-	743,150
Accretion of interest on warrants issued concurrent with a convertible promissory note	-	339,864
Accrued interest on 18% Convertible Promissory Notes	-	7,168
Changes in assets - (increase)/decrease		
Accounts receivable - trade	63,582	40,020
Inventory	(19,483)	(11,956)
Prepaid expenses	(23,711)	(87,286)
Other	(54)	216
Changes in liabilities - increase/(decrease)		
Accounts payable	83,811	(532,354)
Accrued expenses	31,032	(504,354)
Accrued employee compensation	198,581	(22,402)
Interest payable, related parties	18,259	(81,865)
Promissory notes - accrued interest	-	(21,813)
NET CASH USED BY OPERATING ACTIVITIES	(3,007,790)	(5,542,192)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of property and equipment	100,000	-
Purchase of property and equipment	-	(8,859)
NET CASH PROVIDED BY (USED BY) INVESTING ACTIVITIES	100,000	(8,859)
CASH FLOWS FROM FINANCING ACTIVITIES		

Proceeds from 2014 Private Placement, net	-	8,562,500
Proceeds from sale of capital stock - subscription agreement	-	900,000
Proceeds from 18% Convertible Promissory Notes	-	815,000
Proceeds from convertible promissory notes, net	-	325,000
Proceeds from employee stock option exercise	-	12,600
Payments of principal on convertible promissory notes	-	(450,000)
Payments of principal on promissory notes	-	(90,000)
Payments of principal on capital lease	-	(3,951)
NET CASH PROVIDED BY FINANCING ACTIVITIES	-	10,071,149
EFFECT OF EXCHANGE RATES ON CASH	(13,831)	(15,191)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,921,621)	4,504,907
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,547,071	182,315
CASH AND CASH EQUIVALENTS, END OF PERIOD	$625,450	$4,687,222
SUPPLEMENTAL INFORMATION		
Cash paid for interest	$242,904	$325,804

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

1. Nature of the Business

SANUWAVE Health, Inc. and subsidiaries (the "Company") is a shockwave technology company using a patented system of noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. The Company's initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. The Company's lead regenerative product in the United States is the dermaPACE® device, which is in a supplemental Phase III clinical study for treating diabetic foot ulcers.

The Company's portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. Revenues are from sales of the European Conformity Marking ("CE Mark") devices and accessories in Europe, Canada, Asia and Asia/Pacific.

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

2. Going Concern

The continuation of the Company's business is dependent upon raising additional capital before the conclusion of fourth quarter of 2015. As of September 30, 2015, the Company had an accumulated deficit of $91,891,615 and cash and cash equivalents of $625,450. For the nine months ended September 30, 2015 and 2014, the net cash used by operating activities was $3,007,790 and $5,542,192, respectively. The Company incurred a net loss of $3,707,492 for the nine months ended September 30, 2015 and a net loss of $5,974,080 for the year ended December 31, 2014. The operating losses create an uncertainty about the Company's ability to continue as a going concern.

The continuation of the Company's business is dependent upon raising additional capital before the conclusion of fourth quarter of 2015 to fund operations. Management's plans are to obtain additional capital through the issuance of common or preferred stock, securities convertible into common stock or secured or unsecured debt, investments by

strategic partner for market opportunities, which may include strategic partnerships or licensing arrangements or complete a joint venture, partnership or sale of the wound product to complete the FDA trial successfully and begin commercialization of the product in 2016. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. 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.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and footnotes required by United States generally accepted accounting principles for complete financial statements. The financial information as of September 30, 2015 and for the three and nine months ended September 30, 2015 and 2014 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2015 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2015.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

3. Summary of Significant Accounting Policies (continued)

The condensed consolidated balance sheet at December 31, 2014 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements.

Significant Accounting Policies

For further information and a summary of significant accounting policies, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 3, 2015.

Recently Issued Accounting Standards

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional

footnote disclosures). In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2019 instead of the current effective date, which was the first quarter of fiscal 2018. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606)*, deferring the effective date of ASU 2014-09 by one year. The Company can elect to adopt the provisions of ASU 2014-09 for annual periods beginning after December 31, 2017, including interim periods within that reporting period. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on the consolidated financial statements and has not yet determined the method by which the Company will adopt the standard.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, *Simplifying the Measurement of Inventory* (ASU 2015-11), which proposed that inventory should be measured at the lower of cost and net realizable value for inventory that is measured using first-in, first-out (FIFO) or average cost. The main provision of ASU 2015-11 is that an entity should measure inventory at the lower or cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This amendment does not apply to entities that measure inventory using last-in, first-out (LIFO) or the retail inventory method. The standard is effective for public entities for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early application is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the pending adoption of ASU 2015-11 on the consolidated financial statements and has not yet determined the timing at which the Company will adopt the standard.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

4. Property and equipment

Property and equipment consists of the following:

	September 30, 2015	December 31, 2014
Machines and equipment	$240,295	$240,295
Office and computer equipment	166,398	166,398
Software	34,528	34,528
Furniture and fixtures	20,380	20,380
Other assets	2,259	2,259
Total	463,860	463,860
Accumulated depreciation	(458,795)	(456,020)
Net property and equipment	$5,065	$7,840

The aggregate depreciation related to property and equipment charged to operations was $926 and $3,827 for the three months ended September 30, 2015 and 2014, respectively, and $2,775 and $13,312 for the nine months ended September 30, 2015 and 2014, respectively.

5. Intangible assets

Intangible assets consist of the following:

	September 30, 2015	December 31, 2014
Patents, at cost	$3,502,135	$3,502,135

Less accumulated amortization	(3,118,690)	(2,888,622)
Net intangible assets	$383,445	$613,513

The aggregate amortization charged to operations was $76,689 for the three months ended September 30, 2015 and 2014, and $230,068 and $230,067 for the nine months ended September 30, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

6. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
Accrued former executive payment	$125,000	$100,000
Accrued legal professional fees	77,827	111,600
Accrued audit and tax preparation	67,500	55,500
Accrued clinical study expenses	62,495	64,464
Accrued inventory	30,927	-
Accrued board of directors fees	12,000	12,000
Accrued other	24,739	25,892
	$400,488	$369,456

7. Notes payable, related parties

The notes payable, related parties were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. The notes payable, related parties bear interest at 6% per annum. Quarterly interest through June 30, 2010, was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal was due August 1, 2015. The notes payable, related parties had an aggregate outstanding principal balance of $5,342,412, net of $30,331 debt discount at September 30, 2015 and $5,372,743 at December 31, 2014, respectively.

On June 15, 2015, the Company and HealthTronics, Inc. entered into an amendment (the "Note Amendment") to amend certain provisions of the notes payable, related parties. The Note Amendment provides for the extension of the due date to January 31, 2017. In connection with the Note Amendment, the Company entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. The notes payable, related parties will bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default

occurs, the applicable interest rate shall increase by 2% per annum. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company's patents or other intellectual property rights.

In addition, the Company, in connection with the Note Amendment, issued to HealthTronics, Inc. on June 15, 2015, an aggregate total of 3,310,000 warrants (the "Class K Warrants") to purchase shares of the Company's common stock, $0.001 par value (the "Common Stock"), at an exercise price of $0.55 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after ten years.

Accrued interest currently payable totaled $100,123 and $81,864 at September 30, 2015 and December 31, 2014, respectively. Interest expense on notes payable, related parties totaled $100,123 and $81,864 for the three months ended September 30, 2015 and 2014, respectively, and $261,162 and $243,940 for the nine months ended September 30, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

8. Income taxes

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

At September 30, 2015, the Company had federal net operating loss ("NOL") carryforwards of $66,038,028 for tax years through the year ended December 31, 2014, that will begin to expire in 2025. The use of deferred tax assets, including federal net operating losses, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, *Income Taxes*, the Company's management believes that there is not sufficient evidence at September 30, 2015 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2015. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including NOL carryforwards.

The Company's ability to use its NOL carryforwards could be limited and subject to annual limitations. In connection with future offerings, the Company may realize a "more than 50% change in ownership" which could further limit its ability to use its NOL carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which NOL carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take advantage of all or portions of its NOL carryforwards for federal income tax purposes.

9. Equity transactions

2014 Private Placement

On March 17, 2014, in conjunction with a private placement of securities (the "2014 Private Placement") with institutional and select accredited investors, the Company issued an aggregate total of 6,210,000 shares of common stock and 6,175 shares of preferred stock (the "Series A Convertible Preferred Stock") for an aggregate total purchase price of $9,280,000. Each share of Series A Convertible Preferred Stock was convertible into 2,000 shares of common stock at the option of the holder. The proceeds received by the Company were $8,562,500, net of offering costs of $717,500.

The Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 23,200,000 warrants (the "Series A Warrants") to purchase shares of common stock at an exercise price of $0.50 per share. Each Series A Warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expire after five years.

In addition, the Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 13,920,000 warrants (the "Series B Warrants") to purchase shares of common stock at an exercise price of $1.50 per share. Each Series B Warrant represents the right to purchase one share of common stock. The warrants vested upon issuance and expired in March 2015.

Pursuant to the terms of a registration rights agreement that the Company entered with the investors in connection with the 2014 Private Placement, the Company filed a registration statement with the SEC in April 2014 that covered the shares of common stock and the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock and exercise of the Series A Warrants and Series B Warrants issued to the investors in the 2014 Private Placement. The registration statement was declared effective by the SEC on May 6, 2014.

Kevin A. Richardson, II, chairman of the board of directors of the Company and Acting Chief Executive Officer; Joseph Chiarelli, the former Chief Executive Officer of the Company; and, Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, were purchasers in the 2014 Private Placement of $50,000, $40,000 and $50,000, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

9. Equity transactions (continued)

At the closing of the 2014 Private Placement, the Company paid Newport Coast Securities, Inc., the placement agent for the private placement, and Oppenheimer & Co. Inc., the former placement agent, cash compensation based on the gross proceeds of the private placement and 696,000 Series A Warrants and 417,600 Series B Warrants.

18% Convertible Promissory Notes

During the period January 24, 2014 through March 7, 2014, the Company entered into subscriptions payable for 18% convertible promissory notes, as amended, (the "18% Convertible Promissory Notes") from select accredited investors. Up to $1,000,000 aggregate principal amount of 18% Convertible Promissory Notes were offered by the Company. The Company completed the offering and issued an aggregate $815,000 in convertible notes in March 2014. Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, purchased $110,000 of the convertible notes.

The 18% Convertible Promissory Notes had a nine month term from the subscription date and the note holders could convert into Company common stock at anytime during the term at $0.55 per share. Upon the consummation of a qualified financing, as defined in the convertible note agreements, of $1,000,000 or more by the Company, the principal and interest on the 18% Convertible Promissory Notes would convert into Company common stock equal to the lower of (i) the price of the Company common stock issued in the qualified financing, and (ii) $0.55 per share. The note holders would also receive, if any were issued, warrants or any other security issued in a qualified financing on similar terms to the qualified financing. The 18% Convertible Promissory Notes were unsecured.

The 2014 Private Placement was a qualified financing as defined in the 18% Convertible Promissory Notes. As such, on March 17, 2014, in conjunction with the 2014 Private Placement discussed above, the 18% Convertible Promissory Notes, with an aggregate outstanding principal and accrued interest balance of $822,168, were automatically converted and the holders received in the aggregate 1,644,337 shares of common stock, 2,055,421 Series A Warrants, and 1,233,252 Series B Warrants.

Subscription Agreement

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

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

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

On May 27, 2014, the Subscriber paid the Company the remaining $900,000 and was issued 3,600,000 shares of unregistered common stock of the Company as full settlement of the Subscription Agreement.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

9. Equity transactions (continued)

$278,500 Convertible Promissory Note and Warrants

On February 10, 2014, the Company entered into a financing transaction with an accredited investor for the sale of an 8% convertible promissory note (the "$278,500 Convertible Note") and warrants (the "Class J Warrants") in the principal amount of $278,500, with gross proceeds of $250,000 to the Company after payment of a 10% original issue discount and related professional expenses.

The $278,500 Convertible Note and Class J Warrants were issued pursuant to the terms of a purchase agreement among the Company and the holder. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on August 11, 2014. The convertible note accrued interest at the rate of 8% per annum and included a 10%, or $25,000, original issuance discount. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 60 days was 120% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days. The $278,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of the lower of 75% of the lowest reported sale price of the Company's common stock for the 20 trading days immediately prior to (i) the closing date of the financing, or (ii) 75% of the lowest reported sale price for the 20 days prior the conversion date of the convertible note. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

The Class J Warrants entitle the holder to purchase, in the aggregate, 629,378 shares of the Company's common stock. The Warrants were exercisable upon the six month anniversary of the closing date (August 10, 2014) and expire five years from the closing date. The Class J Warrants have an exercise price equal to $0.4425. The Class J Warrants may be exercised for cash or on a cashless basis. The exercise price of the warrants is subject to adjustment for stock splits, combinations or similar events, and, in this event, the number of shares issuable upon the exercise of the warrant will also be adjusted so that the aggregate exercise price shall be the same immediately before and immediately after the adjustment. In addition, the exercise price is also subject to a "down-round" anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price of the warrants.

In March 2014, the Company repaid the $278,500 Convertible Note in full, which totaled $337,171 with accrued interest and a prepayment penalty of $56,195.

$128,500 Convertible Promissory Note

On December 23, 2013, the Company entered into a financing transaction with an accredited investor for the sale of an 8% convertible promissory note (the "$128,500 Convertible Note") in the principal amount of $128,500, with gross proceeds of $125,000 to the Company after payment of related professional expenses.

The $128,500 Convertible Note was issued pursuant to the terms of a purchase agreement among the Company and the accredited investor. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on September 26, 2014. The convertible note accrued interest at the rate of 8% per annum. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 30 days was 115% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days.

The $128,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 61% of the lowest three reported sale prices of the Company's common stock for the 10 trading days immediately prior to the conversion date. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

9. Equity transactions (continued)

In March 2014, the Company repaid the $128,500 Convertible Note in full, which totaled $158,055, with accrued interest and prepayment penalty of $29,555.

$78,500 Convertible Promissory Note

On February 18, 2014, the Company entered into a second tranche of financing with the accredited investor for the $128,500 Convertible Note for the sale of an 8% Convertible Promissory Note (the "$78,500 Convertible Note") under the same terms as the first tranche in the principal amount of $78,500, with gross proceeds of $75,000 to the Company after payment of related professional expenses.

The $78,500 Convertible Note was issued pursuant to the terms of a purchase agreement among the Company and the accredited investor. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on November 20, 2014. The convertible note accrued interest at the rate of 8% per annum. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 30 days was 115% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days.

The $78,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 61% of the lowest three reported sale prices of the Company's common stock for the 10 trading days immediately prior to the conversion date. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

In March 2014, the Company repaid the $78,500 Convertible Note in full, which totaled $90,275 with accrued interest and prepayment penalty of $11,775.

Consulting Agreements

In February 2014, the Company renewed one consulting contract and entered into three additional consulting agreements for which a portion of the fee for the services performed was paid with Company common stock. The Company issued 0 and 1,035,000 shares of common stock under these agreements for the three months and nine months ended September 30, 2014, respectively. The fair value of the common stock issued to the consultants, based upon the closing market price of the Company's common stock at the dates the common stock was issued, was recorded as a non-cash general and administrative expense of $0 and $743,150 for the three and nine months ended September 30, 2014, respectively. The Company did not have any consulting contracts in 2015 where a portion of the fee for services was to be paid with common stock.

10. Preferred Stock

The Company's Articles of Incorporation authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by the board of directors. On March 14, 2014, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series A Convertible Preferred Stock of the Company (the "Certificate of Designation") with the Nevada Secretary of State. The Certificate of Designation amends the Company's Articles of Incorporation to designate 6,175 shares of preferred stock, par value $0.001 per share, as Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock has a stated value of $1,000 per share. On March 17, 2014, in connection with the 2014 Private Placement, the Company issued 6,175 shares of Series A Convertible Preferred Stock (for a more detailed discussion regarding the 2014 Private Placement, see Note 9).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

10. Preferred Stock (continued)

Under the Certificate of Designation, holders of Series A Convertible Preferred Stock are entitled to receive dividends equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. Such holders will participate on an equal basis per-share with holders of common stock in any distribution upon winding up, dissolution, or liquidation of the Company. Holders of Series A Convertible Preferred Stock are entitled to convert each share of Series A Convertible Preferred Stock into 2,000 shares of common stock, provided that after giving effect to such conversion, such holder, together with its affiliates, shall not beneficially own in excess of 9.99% of the number of shares of common stock outstanding (the "Beneficial Ownership Limitation"). Holders of the Series A Convertible Preferred Stock are entitled to vote on all matters affecting the holders of the common stock on an "as converted" basis, provided that such holder shall only vote such shares of Series A Convertible Preferred Stock eligible for conversion without exceeding the Beneficial Ownership Limitation.

In November and December 2014, the holders of Series A Convertible Preferred Stock converted 5,010 shares of Series A Convertible Preferred Stock into 10,020,000 shares of common stock. On January 6, 2015, the holders of Series A Convertible Preferred Stock converted the remaining 1,165 shares of Series A Convertible Preferred Stock into 2,330,000 shares of common stock. As of September 30, 2015, there were no outstanding shares of Series A Convertible Preferred Stock.

11. Warrants

A summary of the warrant activity as of September 30, 2015 and December 31, 2014, and the changes during the nine months ended September 30, 2015, is presented as follows:

Warrant class	Outstanding as of December 31, 2014	Issued	Exercised	Expired	Outstanding as of September 30, 2015
Class E Warrants	3,576,737	-	-	-	3,576,737

Class F Warrants	300,000	-	-	-	300,000
Class G Warrants	1,503,409	-	-	-	1,503,409
Class H Warrants	1,988,095	-	-	-	1,988,095
Class I Warrants	1,043,646	-	-	-	1,043,646
Class J Warrants	629,378	-	-	-	629,378
Class K Warrants	-	3,310,000	-	-	3,310,000
Series A Warrants	25,951,421	-	-	-	25,951,421
Series B Warrants	15,570,852	-	-	(15,570,852)	-
	50,563,538	3,310,000	-	(15,570,852)	38,302,686

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

11. Warrants (continued)

A summary of the warrant exercise price per share and expiration date is presented as follows:

	Exercise price/share	Expiration date
Class E Warrants	$ 4.00	April 2016
Class F Warrants	$ 0.35	February 2018
Class G Warrants	$ 0.80	July 2018
Class H Warrants	$ 0.80	July 2018
Class I Warrants	$ 0.85	September 2018
Class J Warrants	$ 0.44	February 2019
Class K Warrants	$ 0.55	June 2025
Series A Warrants	$ 0.50	March 2019
Series B Warrants	$ 1.50	March 2015

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

The exercise price of the Class J Warrants, Class K Warrants and the Series A Warrants are subject to a “down-round” anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price of the warrants. The Class J Warrants and Class K Warrants may be exercised on a physical settlement or on a cashless basis. The Series A Warrants may be exercised on a physical settlement basis if a registration statement underlying the warrants is effective. If a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale by the holder of the Series A Warrants, then the holder may exercise the warrants on a cashless basis.

The Class J Warrants, the Class K Warrants, the Series A Warrants and the Series B Warrants are derivative financial instruments. The estimated fair value of the Class J Warrants at the date of grant was $12,776. The related debt discount was accreted to interest expense through the maturity date of the related note. The estimated fair value of the

Class K Warrants at the date of grant was $36,989 and recorded as debt discount, which will be accreted to interest expense through the maturity date of the related notes payable, related parties. The estimated fair values of the Series A Warrants and the Series B Warrants at the date of grant were $557,733 for the warrants issued in conjunction with the 2014 Private Placement and $47,974 for the warrants issued in conjunction with the 18% Convertible Promissory Notes. The fair value of the Series A Warrants and Series B Warrants were recorded as equity issuance costs in 2014, a reduction of additional paid-in capital. The Series B Warrants expired unexercised in March 2015.

The estimated fair values were determined using a binomial option pricing model based on various assumptions. The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of derivative liabilities. Various factors are considered in the pricing models the Company uses to value the warrants, including the Company's current common stock price, the remaining life of the warrants, the volatility of the Company's common stock price, and the risk-free interest rate. In addition, as of the valuation dates, management assessed the probabilities of future financing and other re-pricing events in the binominal valuation models.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

11. Warrants (continued)

A summary of the changes in the warrant liability as of September 30, 2015 and December 31, 2014, and the changes during the three and nine months ended September 30, 2015, is presented as follows:

	Class J Warrants	Class K Warrants	Series A Warrants	Series B Warrants	Total
Warrant liability as of December 31, 2014	$3,839	$-	$155,709	$ 78	$159,626
Issued	-	-	-	-	-
Change in fair value	(1,315)	-	(54,633)	(78)	(56,026)
Warrant liability as of March 31, 2015	$2,524	$-	$101,076	$ -	$103,600
Issued	-	36,989	-	-	36,989
Change in fair value	9,154	52,878	367,279	-	429,311
Warrant liability as of June 30, 2015	$11,678	$89,867	$468,355	$ -	$569,900
Issued	-	-	-	-	-
Change in fair value	(6,080)	(50,197)	(246,023)	-	(302,300)
Warrant liability as of September 30, 2015	$5,598	$39,670	$222,332	$ -	$267,600

12. Commitments and contingencies

Operating Leases

Rent expense for the three months ended September 30, 2015 and 2014, was $32,836 and $28,813, respectively and for the nine months ended September 30, 2015 and 2014, was $104,747 and $88,654, respectively.

Litigation

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

13. Stock-based compensation

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Stock Incentive Plan"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to four years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At September 30, 2015 and December 31, 2014, the Stock Incentive Plan reserved 8,500,000 shares of common stock for grant.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

13. Stock-based compensation (continued)

On April 28, 2015, the Company granted two members of the Company's Medical Advisory Board options to purchase 50,000 shares each of the Company's common stock at an exercise price of $0.55 per share in place of an annual cash consulting fee for calendar year 2015. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.1198 resulting in compensation expense of $11,978. Compensation cost will be recognized over calendar year 2015.

On August 31, 2015, the Company granted options to Joseph Chiarelli, the former Chief Executive Officer of the Company as a part of a confidential Settlement Agreement and Mutual Releases agreement. Using the Black-Scholes options pricing model, management has determined that the fair value per share resulted in compensation expense of $98,100. Compensation cost was recognized at the date of grant.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the nine months ended September 30, 2015 and 2014:

	2015		2014	
Weighted average expected life in years	5.0		5.5	
Weighted average risk free interest rate	1.51	%	1.81	%
Weighted average volatility	121.9	%	138.0	%
Forfeiture rate	0.0	%	0.0	%
Expected dividend yield	0.0	%	0.0	%

The expected life of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. Since there is a limited trading history for the Company's common stock, the expected volatility is based on a combination of historical data from companies similar in size, value and trading history for the Company's common stock. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. Management estimates pre-vesting forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest. The expected dividend yield is based on

historical dividend experience, however, since inception the Company has not declared dividends.

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, $96,323 and $94,032 for the three months ended September 30, 2015 and 2014, respectively and $146,385 and $369,238 for the nine months ended September 30, 2015 and 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

13. Stock-based compensation (continued)

A summary of option activity as of September 30, 2015 and December 31, 2014, and the changes during the three and nine months ended September 30, 2015, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2014	7,206,830	$ 1.31
Granted	-	$ -
Exercised	-	$ -
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of March 31, 2015	7,206,830	$ 1.31
Granted	100,000	$ 0.55
Exercised	-	$ -
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of June 30, 2015	7,306,830	$ 1.30
Granted	1,500,000	$ 0.51
Exercised	-	$ -
Cancelled	-	$ -
Forfeited or expired	(872,759)	$ 0.36
Outstanding as of September 30, 2015	7,934,071	$ 1.25
Exercisable	7,734,069	$ 1.28

The range of exercise prices for options was $0.21 to $2.92 for options outstanding at September 30, 2015 and December 31, 2014. The aggregate intrinsic value for all vested and exercisable options was $0 at September 30, 2015 and December 31, 2014.

The weighted average remaining contractual term for outstanding exercisable stock options was 5.06 and 6.43 years as of September 30, 2015 and December 31, 2014, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

13. Stock-based compensation (continued)

A summary of the Company's nonvested options as of September 30, 2015 and December 31, 2014, and changes during the three and nine months ended September 30, 2015, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2014	914,542	$ 0.37
Granted	-	$ -
Vested	(631,208)	$ 0.35
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of March 31, 2015	283,334	$ 0.43
Granted	100,000	$ 0.55
Vested	(141,666)	$ 0.55
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of June 30, 2015	241,668	$ 0.41
Granted	1,500,000	$ 0.51
Vested	(1,525,000)	$ 0.51
Cancelled	-	$ -
Forfeited or expired	(16,666)	$ 0.55
Outstanding as of September 30, 2015	200,002	$ 0.38

14. Earnings (loss) per share

The Company calculates net income (loss) per share in accordance with ASC 260, *Earnings Per Share*. Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then

outstanding. To the extent that securities are “anti-dilutive,” they are excluded from the calculation of diluted net income (loss) per share.

As a result of the net loss for the nine months ended September 30, 2015 and 2014, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive equity securities totaled 46,236,757 shares and 70,170,368 shares at September 30, 2015 and 2014, respectively.

15. Subsequent events

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

In October 2015, the board of directors of the Company approved increasing the number of authorized shares in the Amended and Restated 2006 Stock Incentive Plan 12,500,000. In October 2015, the board of directors of the Company granted additional stock options to certain employees, members of the board of directors and advisors of the Company.

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, 2014 included in our Annual Report on Form 10-K, filed with the SEC on March 3, 2015.

Overview

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

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

We believe we have demonstrated that our patented technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe, Asia and Asia/Pacific. Our lead product candidate for the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

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

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

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

Recent Developments

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a supplemental clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. Patient enrollment began in June 2013 and as of April 30, 2014, we had enrolled the minimum number of 90 patients in the clinical trial, which represented the number of patients for the first interim analysis by the independent Data Monitoring Committee (DMC). In September 2014, we reported that the independent Data Monitoring Committee had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the clinical trial and recommended we continue enrollment of patients into the study up to the next predefined patient analysis point of 130 patients. We completed enrollment for the 130 patients in November 2014 and suspended further enrollment at that time.

The DMC performed an analysis of the primary efficacy endpoint of the rate of 100% complete wound closure at the 12-week endpoint for the dermaPACE treated patients as compared to the sham-control patients and the safety data. The DMC has completed its review and noted there were no safety issues. The DMC reported the Monitoring Success Criterion for primary efficacy endpoint of 100% complete wound closure at 12 weeks has not been met and, assuming similar trends for any additional patents enrolled, will likely not be met at the next predefined analysis point of 170 patients. The Monitoring Success Criterion is a predictive probability of dermaPACE achieving statistical significance in the rate of 100% complete wound closure at 12 weeks as compared to the rate for sham-control.

As per its charter, the DMC's review was limited to only the 12-week endpoint data. The DMC has requested to us the ability to review complete closure rates at later points in the study, as patients were followed for up to 24 weeks and the DMC noted we had positive results in the first study of 206 patients completed in 2011 at the 20-week endpoint.

We have retained Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in January 2015 to lead the Company's interactions and correspondence with the FDA for the dermaPACE, which have already commenced. MCRA has successfully worked with the FDA on numerous Premarket Approvals (PMAs) for various musculoskeletal, restorative and general surgical devices since 2006.

We, including our regulatory advisor MCRA, held an in-person meeting with the FDA in June 2015 and in this meeting, it was determined that the best path would be for us to retain the original analysis plan. In addition, the FDA noted the totality of the data from the clinical study, such as additional endpoints and a favorable risk/benefit profile, will play an important role in the FDA's review of our PMA submission.

All 130 of the patients enrolled as of November 2014 have completed the full 24-week follow-up at this time. We worked with our Clinical Research Organization (CRO), CPC Clinical Research, Inc., to complete the auditing of the clinical documentation at each clinical site, perform site close-out visits, complete a final review and then locked the clinical study database in August 2015. We have conducted preliminary statistical analyses and announced that we did not reach statistical significance at 12 weeks, however our clinical study did show efficacy at 20 weeks when combining the two trials. There were no serious or related adverse events associated with dermaPACE treatment reported during the course of the two studies and there were no issues regarding the tolerability of the treatment. Due to the safety profile of our device and the efficacy of the data at 20 weeks, we are moving forward with our PMA submission to the FDA and expect to make our submission in early first quarter of 2016. We will be working with MCRA in developing a submission strategy and to serve as the key element in communication with FDA during the pre and post PMA submission process.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the pivotal trial (discussed below). Similar to the pivotal trial, four dermaPACE procedures are administered during the first two weeks following subject enrollment. In the current trial, however, up to four additional dermaPACE procedures are delivered

bi-weekly, between weeks 4 and 10 following subject enrollment, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

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

Our dermaPACE device has received the European CE Mark approval to treat acute and chronic defects of the skin and subcutaneous soft tissue, such as in the treatment of pressure ulcers, diabetic foot ulcers, burns, and traumatic and surgical wounds. We are currently marketing the dermaPACE to the European Community, Canada and Asia/Pacific, utilizing distributors in select countries.

Previous clinical work supporting our current dermaPACE clinical study

The dermaPACE device completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA Application was filed with the FDA in July 2011. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

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

A summary of the key study findings were as follows:

Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of sham-control subjects (p=0.047); in the efficacy evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of sham-control subjects (p=0.018).

Subjects treated with dermaPACE achieved a significant increase in the rate of complete and/or ≥90% wound closure. We analyzed a clinically relevant ≥ 90% wound closure endpoint that demonstrated statistical significance (p=0.0161) in favor of dermaPACE subjects (51/107, 48%) compared to patients randomized to receive sham-control (31/99, 31%).

Within 6 weeks following the initial dermaPACE treatment, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control (p<0.05).

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

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

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

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's failure to meet the study's primary endpoint of 100% wound closure compared with sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency was for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we decided to conduct supplemental clinical work, as discussed above.

Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2015, we had cash and cash equivalents totaling $625,450. Management believes that these funds will support our operations into the fourth quarter of 2015. Management expects the cash used in operations for the Company during the remainder of 2015 will be approximately $200,000 to $250,000 per month, exclusive of FDA submission costs, as resources are devoted to the review and analysis of the clinical data results phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers.

We do not currently generate significant recurring revenue and will require additional capital before the conclusion of fourth quarter of 2015. We may raise capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, an investment by a strategic partner in a specific clinical indication or market opportunity, or by selling all or a portion of the Company's assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions should provide the necessary funding for us.

Since our inception, we have incurred losses from operations each year. As of September 30, 2015, we had an accumulated deficit of $91,891,615. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next several years as we continue to fund the dermaPACE clinical trial and the FDA approval process.

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

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

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth

under the section entitled “Risk Factors – Risks Related to Our Business” in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 3, 2015.

Critical Accounting Policies and Estimates

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

On an ongoing basis, we evaluate our estimates and judgments, including those related to the recording of the allowances for doubtful accounts, estimated reserves for inventory, estimated useful life of property and equipment, the determination of the valuation allowance for deferred taxes, the estimated fair value of the warrant liability, the estimated fair value of stock-based compensation, and the estimated fair value of intangible assets. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements filed with our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 3, 2015, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, intangible assets, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

Research and Development Costs

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

Inventory Valuation

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

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

Intangible Assets

Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over the average life of 11.4 years. We regularly review intangible assets to determine if facts and circumstances indicate that the useful life is shorter than we originally estimated or that the carrying amount of the assets may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the intangible assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If recognition of an impairment charge is necessary, it is measured as the amount by which the carrying amount of the intangible asset exceeds the fair value of the intangible asset.

Stock-based Compensation

The Stock Incentive Plan provides that stock options, and other equity interests or equity-based incentives, may be granted to key personnel, directors and advisors at the fair value of the common stock at the time the option is granted, which is approved by our board of directors. The maximum term of any option granted pursuant to the Stock Incentive Plan is ten years from the date of grant.

In accordance with ASC 718, *Compensation – Stock Compensation*, 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*. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets, including loss carryforwards, when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We account for uncertain tax positions in accordance with the related provisions of ASC 740, *Income Taxes*. ASC 740 specifies the way public companies are to account for uncertainties in income tax reporting, and prescribes a methodology for recognizing, reversing, and measuring the tax benefits of a tax position taken, or expected to be taken, in a tax return. ASC 740 requires the evaluation of tax positions taken or expected to be taken in the course of preparing our tax returns to determine whether the tax positions would “more-likely-than-not” be sustained if challenged by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax benefit or expense in the current year.

Results of Operations for the Three Months ended September 30, 2015 and 2014 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended September 30, 2015 were $143,605, compared to $227,492 for the same period in 2014, a decrease of $83,887, or 37%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The decrease in revenues for 2015 was due to lower sales of orthoPACE devices and applicators in Europe.

Cost of revenues for the three months ended September 30, 2015 were $38,752, compared to $68,077 for the same period in 2014. Gross profit as a percentage of revenues was 73% for the three months ended September 30, 2015, compared to 70% for the same period in 2014. The increase in gross profit as a percentage of revenues in 2015 was due to sale of four devices in 2014, which have a lower margin than applicators, compared to the sale of one device in 2015.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2015 were $569,134, compared to $708,304 for the same period in 2014, a decrease of $139,170, or 20%. 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 monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs. Research and development expenses decreased in 2015 as a result of lower payments to third party clinical sites participating in the dermaPACE clinical study as there were fewer active patients in the clinical study in 2015 as compared to 2014. This is partially offset by higher consulting related costs as we review the data results and prepare to file our PMA with the FDA.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2015 were $778,679, as compared to $780,115 for the same period in 2014, a decrease of $1,436. The decrease in general and administrative expenses is primarily due to reduced consulting expenses and is mostly offset by higher non-cash stock compensation expense and higher legal fees related to employee matters and patent filings in 2015.

Other Income (Expense)

Other income (expense) was a net income of $293,731 for the three months ended September 30, 2015, as compared to a net expense of ($83,385) for the same period in 2014, an increase in other income (expense) of $377,116. The increase in other income (expense) for 2015 was due to gain on warrant valuation of $302,300 related to the change in the fair value of the warrants issued in 2014 and 2015 and a gain of sale of property and equipment of $100,000 related to the sale of OssaTron inventory to Premier Shockwave. This is partially offset by increased interest expense of $25,875 related to the amendment to the notes payable, related parties.

Provision for Income Taxes

At September 30, 2015, we had federal net operating loss carryforwards of $66,038,028 through the year ended December 31, 2014 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the three months ended September 30, 2015 was $1,026,844, or ($0.02) per basic and diluted share, compared to a net loss of $1,492,905, or ($0.03) per basic and diluted share, for the same period in 2014, a decrease in the net loss of $466,061, or 31%. The decrease in the net loss for 2015 was primarily a result of the reduced operating expenses as discussed above, the gain on warrant valuation adjustment of $302,300 and the gain on sale of property and equipment of $100,000 offset by higher interest expense and lower sales.

We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device clinical trial for the treatment of diabetic foot ulcers and the related FDA approval process, assuming positive clinical results.

Results of Operations for the Nine Months ended September 30, 2015 and 2014 (Unaudited)

Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2015 were $594,040, compared to $610,705 for the same period in 2014, a decrease of $16,665, or 3%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The decrease in revenues for 2015 was mainly due to the impact of the changes in foreign currently rates primarily for sales in Euros as there are higher sales of orthoPACE devices and applicators in 2015.

Cost of revenues for the nine months ended September 30, 2015 were $173,349, compared to $149,813 for the same period in 2014. Gross profit as a percentage of revenues was 71% for the nine months ended September 30, 2015, compared to 76% for the same period in 2014. The decrease in gross profit as a percentage of revenues in 2015 was due to the combination of one more device sale in 2015 as compared to 2014, and twenty-one less wound kits sold in 2015 as compared to 2014. Device sales have a low margin and wound kits have a high margin.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2015 were $1,660,546, as compared to $2,486,801 for the same period in 2014, a decrease of $826,255, or 33%. 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 monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs. Research and development expenses decreased in 2015 as a result of lower headcount in the clinical department and lower payments to third party clinical sites participating in the dermaPACE clinical study as there were fewer active patients in the clinical study in 2015 as compared to 2014.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2015 were $1,981,541, as compared to $2,774,828 for the same period in 2014, a decrease of $793,287, or 29%. The decrease in general and administrative expenses is primarily due to reduced consulting expenses which are partially offset by higher legal fees related to employee matters and patent filings in 2015.

Other Expense

Other expense was $253,253 for the nine months ended September 30, 2015, as compared to $706,393 for the same period in 2014, a decrease in other expense of $453,140, or 64%. The decrease in other expense for 2015 was due to $460,118 in interest expense recorded in 2014 related to promissory notes repaid in full in March 2014 and gain on sale of property and equipment of $100,000 in 2015, which was offset by loss on warrant valuation adjustment of $70,985 and increase interest expense related to notes payable, related parties of $17,222 in 2015.

Provision for Income Taxes

At September 30, 2015, we had federal net operating loss carryforwards of $66,038,028 through the year ended December 31, 2014 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the nine months ended September 30, 2015 was $3,707,492, or ($0.06) per basic and diluted share, compared to a net loss of $5,750,509, or ($0.12) per basic and diluted share, for the same period in 2014, a decrease in the net loss of $2,043,017, or 36%. The decrease in the net loss for 2015 was primarily a result of the reduced operating expenses of $1,619,542 and reduced other expenses of $453,140 as discussed above.

We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device clinical trial for the treatment of diabetic foot ulcers and the related FDA approval process, assuming positive clinical results.

Liquidity and Capital Resources

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2015, we had cash and cash equivalents totaling $625,450. For the nine months ended September 30, 2015 and 2014, the net cash used by operating activities was $3,007,790 and $5,542,192, respectively. Since inception, we have experienced recurring losses from operations and had an accumulated deficit of $91,891,615 at September 30, 2015.

The continuation of our business is dependent upon raising additional capital before the conclusion of fourth quarter of 2015 to fund operations. Management’s plans are to obtain additional capital through the issuance of common or preferred stock, securities convertible into common stock or secured or unsecured debt, investments by strategic partner for market opportunities, which may include strategic partnerships or licensing arrangements or complete a joint venture, partnership or sale of the wound product to complete the FDA trial successfully and begin commercialization of the product in 2016. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us to continue as a going concern. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. The condensed consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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

Cash and cash equivalents decreased by $2,921,621 for the nine months ended September 30, 2015 and increased by $4,504,907 for the nine months ended September 30, 2014. For the nine months ended September 30, 2015 and 2014, net cash used by operating activities was $3,007,790 and $5,542,192, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for the nine months ended September 30, 2015, as compared to the same period for 2014, of $2,534,402, or 46%, was primarily due to the decreased operating expenses in 2015, as compared to 2014, and the reduction of accounts payable and accrued expenses in 2014. Net cash provided by financing activities for the nine months ended September 30, 2014 was $10,071,149, which primarily consisted of the net proceeds from the 2014 Private Placement of $8,562,500, the proceeds from the 18% Convertible Promissory Notes of $815,000 and the proceeds from sale of capital stock per the Subscription Agreement with a related party of $900,000.

Segment and Geographic Information

We have determined that we are principally engaged in one operating segment. Our products are primarily used for the repair and regeneration of tissue, musculoskeletal and vascular structures in wound healing and orthopedic conditions. Our revenues are generated from sales in Europe, Canada, Asia and Asia/Pacific.

Contractual Obligations

Our major outstanding contractual obligations relate to our operating lease for our facility, purchase and supplier obligations for product component materials and equipment, and our notes payable. We have disclosed these obligations in our most recent Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 3, 2015.

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.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act are accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation under the supervision and with the participation of our management, including our Acting Chief Executive Officer (principal executive officer) and interim Chief Financial Officer (principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2015. Based on this evaluation, the Acting Chief Executive Officer and interim Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2015.

We had previously reported, as of December 31, 2014, a material weakness in the our internal control over financial reporting process for the lack of internal expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions related to complex financial instruments and derivatives. A “material weakness” is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis by the company’s internal controls. Management believes the material weakness identified was due to the complex and non-routine nature of our complex financial instruments and derivatives.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting, except we added a control for management to engage, as necessary, an outside consultant to assist in the application of United States generally accepted accounting principles to complex transactions such as complex financial instruments and derivatives.

PART II — OTHER INFORMATION

Item 6. EXHIBITS

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).
3.4	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14A filed with the SEC on June 25, 2015).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
3.6	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Principal Executive Officer.

32.2* Section 1350 Certification of the Chief Financial Officer.

101.INS*† XBRL Instance.

101.SCH*† XBRL Taxonomy Extension Schema.

101.CAL*† XBRL Taxonomy Extension Calculation.

101.DEF*† XBRL Taxonomy Extension Definition.

101.LAB*† XBRL Taxonomy Extension Labels.

101.PRE*† XBRL Taxonomy Extension Presentation.

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* Filed herewith.

† XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

SIGNATURES

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

Dated: November 12, 2015

SANUWAVE HEALTH, INC.

By: /s/ *Kevin A. Richardson II*
Kevin A. Richardson II
Acting Chief Executive Officer

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

Signatures	**Capacity**	**Date**
By: */s/Kevin A. Richardson II* Name: Kevin A. Richardson II	Acting Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	November 12, 2015
By: */s/ Lisa E. Sundstrom* Name: Lisa E. Sundstrom	Controller and interim Chief Financial Officer (principal financial and accounting officer)	November 12, 2015
By*: /s/ John F. Nemelka* Name: John F. Nemelka	Director	November 12, 2015
By*: /s/ Alan L. Rubino* Name: Alan L. Rubino	Director	November 12, 2015

EXHIBIT INDEX

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3.4	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14A filed with the SEC on June 25, 2015).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
3.6	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Principal Executive Officer.
32.2*	Section 1350 Certification of the Chief Financial Officer.

101.INS*†XBRL Instance.

101.SCH*†XBRL Taxonomy Extension Schema.

101.CAL*†XBRL Taxonomy Extension Calculation.

101.DEF*†XBRL Taxonomy Extension Definition.

101.LAB*†XBRL Taxonomy Extension Labels.

101.PRE*†XBRL Taxonomy Extension Presentation.

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* Filed herewith.

† XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.