

SANUWAVE Health, Inc.  
Form 10-Q  
May 15, 2017

**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 March 31, 2017**

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)

<b>Nevada</b>	<b>20-1176000</b>
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
<b>3360 Martin Farm Road, Suite 100</b>	<b>30024</b>

**Suwanee, GA**

(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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 10, 2017, there were issued and outstanding 139,015,329 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, the Company’s near term cash requirements and cash sources, 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 “continue,” the negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission (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, 2016, filed on March 31, 2017 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, 2016, filed on March 31, 2017.

*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)

	March 31, 2017	December 31, 2016
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$97,538	\$133,571
Accounts receivable, net of allowance for doubtful accounts of \$40,348 in 2017 and \$35,196 in 2016	451,369	460,799
Inventory	202,879	231,953
Prepaid expenses	115,377	87,823
<b>TOTAL CURRENT ASSETS</b>	<b>867,163</b>	<b>914,146</b>
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4)	70,818	76,938
OTHER ASSETS	13,841	13,786
<b>TOTAL ASSETS</b>	<b>\$951,822</b>	<b>\$1,004,870</b>
<b>LIABILITIES</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$1,033,341	\$712,964
Accrued expenses (Note 5)	546,829	375,088
Accrued employee compensation	64,860	64,860
Interest payable, related parties (Note 6)	246,264	109,426
Short term loan, net (Note 7)	100,000	47,440
Warrant liability (Note 11)	861,525	1,242,120
Notes payable, related parties, net (Note 6)	5,367,912	5,364,572
<b>TOTAL LIABILITIES</b>	<b>8,220,731</b>	<b>7,916,470</b>
<b>COMMITMENTS AND CONTINGENCIES (Note 12)</b>		
<b>STOCKHOLDERS' DEFICIT</b>		
PREFERRED STOCK, SERIES A CONVERTIBLE, par value \$0.001, 6,175 authorized; 6,175 shares issued and 0 shares outstanding in 2017 and 2016 (Note 10)	-	-
	-	-

PREFERRED STOCK, SERIES B CONVERTIBLE, par value \$0.001, 293 authorized; 293 shares issued and 0 shares outstanding in 2017 and 2016, respectively (Note 10)		
PREFERRED STOCK - UNDESIGNATED, par value \$0.001, 4,993,532 shares authorized; no shares issued and outstanding (Note 10)	-	-
COMMON STOCK, par value \$0.001, 350,000,000 shares authorized; 138,815,329 and 137,219,968 issued and outstanding in 2017 and 2016, respectively (Note 9)	138,815	137,220
ADDITIONAL PAID-IN CAPITAL	92,569,540	92,436,697
ACCUMULATED DEFICIT	(99,926,980)	(99,433,448)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(50,284 )	(52,069 )
TOTAL STOCKHOLDERS' DEFICIT	(7,268,909 )	(6,911,600 )
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$951,822	\$1,004,870

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

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

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
REVENUES	\$ 149,569	\$ 269,324
COST OF REVENUES (exclusive of depreciation and amortization shown below)	55,144	73,181
OPERATING EXPENSES		
Research and development	260,338	309,955
General and administrative	448,606	499,132
Depreciation	6,120	836
Amortization	-	76,689
Gain of sale of assets, property and equipment	-	(1,000 )
TOTAL OPERATING EXPENSES	715,064	885,612
OPERATING LOSS	(620,639 )	(689,469 )
OTHER INCOME (EXPENSE)		
Gain (loss) on warrant valuation adjustment and conversion	323,223	(797,697 )
Interest expense, net	(192,738 )	(234,430 )
Loss on foreign currency exchange	(3,378 )	(2,980 )
TOTAL OTHER INCOME (EXPENSE), NET	127,107	(1,035,107 )
NET LOSS	(493,532 )	(1,724,576 )
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	1,785	2,972
TOTAL COMPREHENSIVE LOSS	\$(491,747 )	\$(1,721,604 )
LOSS PER SHARE:		
Net loss - basic and diluted	\$0.00	\$(0.02 )
Weighted average shares outstanding - basic and diluted	138,042,070	75,220,485

The accompanying notes to condensed consolidated financial



statements are an integral part of these statements.

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

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(493,532)	\$(1,724,576)
Adjustments to reconcile net loss to net cash used by operating activities		
Depreciation	6,120	836
Change in allowance for doubtful accounts	5,152	1,052
Amortization	-	76,689
Stock-based compensation - employees, directors and advisors	-	4,500
(Gain) loss on warrant valuation adjustment	(323,223)	873,118
Amortization of debt discount	55,900	5,694
Amortization of debt issuance costs	-	74,549
Gain on sale of asset, property and equipment	-	(1,000 )
Changes in assets - (increase)/decrease		
Accounts receivable - trade	4,278	27,370
Inventory	29,074	26,413
Prepaid expenses	(27,554 )	(23,530 )
Other	(55 )	(94 )
Changes in liabilities - increase/(decrease)		
Accounts payable	320,377	(153,022 )
Accrued expenses	171,741	(107,371 )
Accrued employee compensation	-	44,613
Interest payable, related parties	136,838	(56,835 )
Promissory notes, accrued interest	-	(79,948 )
<b>NET CASH USED BY OPERATING ACTIVITIES</b>	<b>(114,884)</b>	<b>(1,011,542)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Proceeds from sale of property and equipment	-	1,000
<b>NET CASH PROVIDED BY INVESTING ACTIVITIES</b>	<b>-</b>	<b>1,000</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from warrant exercise	77,066	-
Proceeds from 2016 Public Offering, net	-	1,352,775
Proceeds from convertible promissory notes, net	-	106,000
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>77,066</b>	<b>1,458,775</b>
<b>EFFECT OF EXCHANGE RATES ON CASH</b>	<b>1,785</b>	<b>2,972</b>

NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(36,033 )	451,205
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	133,571	152,930
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$97,538	\$604,135
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	\$-	\$209,549

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

## **SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

### **NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

#### **1. Nature of the Business**

SANUWAVE Health, Inc. and subsidiaries (the “Company”) is an acoustic shock wave technology company using a patented system of noninvasive, high-energy, acoustic pressure shock waves for regenerative medicine and other applications. The Company’s initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic shock waves 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, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. The results of these clinical studies were submitted to the U.S. Food and Drug Administration (“FDA”) in late July 2016, after our in-person meeting to discuss the submission strategy, for possible approval in the second half of 2017.

The Company’s portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. The Company currently does not market any commercial products for sale in the United States. Revenues are from sales of the European Conformity Marking (“CE Mark”) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

#### **2. Going Concern**

The Company does not currently generate significant recurring revenue and will require additional capital during the second quarter of 2017. As of March 31, 2017, the Company had an accumulated deficit of \$99,926,980 and cash and cash equivalents of \$97,538. For the three months ended March 31, 2017 and 2016, the net cash used by operating activities was \$114,884 and \$1,011,542, respectively. The Company incurred a net loss of \$493,532 for the three months ended March 31, 2017 and a net loss of \$6,439,040 for the year ended December 31, 2016. 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 during the second quarter of 2017 to fund operations. Management’s plans are to obtain additional capital in 2017 through investments by strategic

partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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 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 March 31, 2017 and for the three months ended March 31, 2017 and 2016 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2017 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2017.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**3. Summary of Significant Accounting Policies (continued)**

The condensed consolidated balance sheet at December 31, 2016 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, 2016, filed with the SEC on March 31, 2017.

**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.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**3. Summary of Significant Accounting Policies (continued)**

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 of 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 elected early adoption of this guidance as it more reasonably states inventory and adopted ASU 2015-11 effective January 1, 2016.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. This ASU provides guidance that simplifies the presentation of deferred income taxes. This ASU requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The implementation of this ASU is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on the balance sheet. The provisions of this guidance are effective for the annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. Management is evaluating the requirements of this guidance and has not yet determined the impact of the pending adoption on the Company's financial position or results of operations.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation (Topic 718)*. This ASU provides guidance to simplify several aspects of the accounting for share-based payments transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for annual and interim periods beginning after December 31, 2016. Early adoption is permitted for an entity in an interim or annual period. We have evaluated the effect the updated standard will have on our financial statements, with the effect of the guidance adding modest volatility in our equity-based compensation expense, provision for income taxes, and net income (loss).



In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments (Topic 230)*. This ASU will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The ASU will be effective for fiscal years beginning after December 15, 2017. This standard will require adoption on a retrospective basis unless it is impracticable to apply, in which case it would be required to apply the amendments prospectively as of the earliest date practicable. Management is evaluating the requirements of this guidance and has not yet determined the impact of the adoption on the Company's financial position or results of operations.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2017****4. Property and equipment**

Property and equipment consists of the following:

	March 31, 2017	December 31, 2016
Machines and equipment	\$240,295	\$240,295
Office and computer equipment	156,860	156,860
Devices	82,204	82,204
Software	34,528	34,528
Furniture and fixtures	16,019	16,019
Other assets	2,259	2,259
Total	532,165	532,165
Accumulated depreciation	(461,347)	(455,227)
Net property and equipment	\$70,818	\$76,938

Depreciation expense was \$6,120 and \$836 for the three months ended March 31, 2017 and 2016, respectively.

**5. Accrued expenses**

Accrued expenses consist of the following:

	March 31, 2017	December 31, 2016
Deposits	\$158,000	\$-

Accrued executive severance	100,000	100,000
Deferred rent	49,841	41,341
Accrued outside services	47,615	31,533
Accrued audit and tax preparation	45,000	100,000
Deferred revenue	33,824	18,810
Accrued board of director's fees	32,000	16,000
Accrued executive compensation	30,000	-
Accrued legal professional fees	29,184	45,000
Accrued clinical study expenses	13,650	13,650
Accrued other	7,715	8,754
	\$546,829	\$375,088

## 6. 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 bore 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.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**6. Notes payable, related parties (continued)**

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 provided for the extension of the due date to January 31, 2017. In the period ending March, 31, 2016, the Company reclassified the outstanding principal balance from non-current liabilities to current liabilities. 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.

On June 28, 2016, the Company and HealthTronics, Inc. entered into a second amendment (the “Second Amendment”) to amend certain provisions of the notes payable, related parties. The Second Amendment provides for the extension of the due date to January 31, 2018.

The notes payable, related parties had an aggregate outstanding principal balance of \$5,367,912, net of \$4,831 debt discount at March 31, 2017 and \$5,364,572, net of \$8,171 debt discount at December 31, 2016, respectively.

In addition, the Company, in connection with the Note Amendment, issued to HealthTronics, Inc. on June 15, 2015, a 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. The fair value of these warrants on the date of issuance was \$0.0112 and \$36,989 was recorded as a debt discount to be amortized over the life of the amendment.

In addition, the Company, in connection with the Second Amendment, issued to HealthTronics, Inc. on June 28, 2016, an additional 1,890,000 Class K Warrants to purchase shares of the Company’s Common Stock at an exercise price of \$0.08 per share, subject to certain anti-dilution protection. The exercise price of the 3,310,000 Class K Warrants

issued on June 15, 2015 was decreased to \$0.08 per share. The fair value of these warrants on the date of issuance was \$0.005 and \$9,214 was recorded as a debt discount to be amortized over the life of the amendment.

Accrued interest currently payable totaled \$246,264 and \$109,426 at March 31, 2017 and December 31, 2016, respectively. Interest expense on notes payable, related parties totaled \$140,178 and \$152,713 for the three months ended March 31, 2017 and 2016, respectively.

## **7. Short term loan**

On December 21, 2016, the Company entered into a short term loan with Millennium Park Capital LLC (the “Holder”) in the principal amount of \$100,000. The principal amount shall be due and payable on March 31, 2017, or on the date that money is obtained from the Company’s Korean distributor, or date that money is obtained from a new distributor.

In addition, the Company will issue to the Holder 500,000 warrants to purchase shares of the Company’s common stock, \$0.001 par value (the “Common Stock”), at an exercise price of \$0.17. Each warrant will represent the right to purchase one share of Common Stock. The warrants will vest upon issuance and have an expiration date of March 17, 2019. The fair value of these warrants on the date of issuance \$0.1168, using the Black-Scholes option pricing model, and \$58,400 was recorded as a debt discount to be amortized over the life of the short term loan.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**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 2007.

At March 31, 2017, the Company had federal net operating loss (“NOL”) carryforwards for tax years through the year ended December 31, 2016, 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 March 31, 2017 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2017. 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**

**Warrant Exercise**

On March 10, 2017, the Company issued 363,333 shares of common stock upon the exercise of 363,333 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant Public Offering agreement. The Company received proceeds of \$29,066.

On January 24, 2017, the Company issued 600,000 shares of common stock upon the exercise of 600,000 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant Public Offering agreement. The Company received proceeds of \$48,000.

On October 20, 2016, the Company issued 185,000 shares of common stock upon the exercise of 185,000 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant agreement.

On October 14, 2016, the Company issued 258,333 shares of common stock upon the exercise of 258,333 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant agreement.

On September 20, 2016, the Company issued 400,000 shares of common stock upon the exercise of 400,000 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant agreement.

**Cashless Warrant Exercise**

On March 13, 2017, the Company issued 297,035 shares of common stock to Lucas Hoppel upon the cashless exercise of 583,333 Class L Warrants to purchase shares of stock for \$0.08 per share based on a current market value of \$0.163 per share as determined under the terms of the Class L Warrant Private Offering agreement.

On February 6, 2017, the Company issued 80,804 shares of common stock to Intracoastal Capital, LLC upon the cashless exercise of 100,000 Series A Warrants to purchase shares of stock for \$0.0334 per share based on a current market value of \$0.174 per share as determined under the terms of the Series A Warrant agreement.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**9. Equity transactions (continued)**

On February 2, 2017, the Company issued 158,240 shares of common stock to Intracoastal Capital, LLC upon the cashless exercise of 200,000 Series A Warrants to purchase shares of stock for \$0.0334 per share based on a current market value of \$0.17 per share as determined under the terms of the Series A Warrant agreement.

On January 26, 2017, the Company issued 79,998 shares of common stock to Intracoastal Capital, LLC upon the cashless exercise of 100,000 Series A Warrants to purchase shares of stock for \$0.0334 per share based on a current market value of \$0.1669 per share as determined under the terms of the Series A Warrant agreement.

On January 20, 2017, the Company issued 15,951 shares of common stock to Intracoastal Capital, LLC upon the cashless exercise of 20,000 Series A Warrants to purchase shares of stock for \$0.0334 per share based on a current market value of \$0.165 per share as determined under the terms of the Series A Warrant agreement.

On November 18, 2016, the Company issued 117,510 shares of common stock to DeMint Law, PLLC upon the cashless exercise of 143,400 Series A Warrants to purchase shares of stock for \$0.0334 per share based on a current market value of \$0.185 per share as determined under the terms of the Series A Warrant agreement.

On September 8, 2016, the Company issued 526,288 shares of common stock to Vigere Capital LP upon the cashless exercise of 971,667 Class M Warrants to purchase shares of stock for \$0.06 per share based on a current market value of \$0.11 per share as determined under the terms of the Class M Warrant agreement.

On August 23, 2016, the Company issued 343,434 shares of common stock to JDF Capital, Inc. upon the cashless exercise of 971,667 Class M Warrants to purchase shares of stock for \$0.06 per share based on a current market value of \$0.17 per share as determined under the terms of the Class M Warrant agreement.



On August 23, 2016, the Company issued 1,640,589 shares of common stock to JDF Capital, Inc. upon the cashless exercise of 4,641,667 Class J Warrants to purchase shares of stock for \$0.06 per share based on a current market value of \$0.17 per share as determined under the terms of the Class J Warrant agreement.

**2016 Private Placement**

On August 11, 2016, the Company began a private placement of securities (the “2016 Private Placement”) with select accredited investors in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), an Rule 506 of Regulation D (“Regulation D”) as promulgated by the United States Securities and Exchange Commission (the “Commission”) under the Securities Act. The 2016 Private Placement offered Units (the “Units”) at a purchase price of \$0.06 per Unit, with each Unit consisting of (i) one (1) share of our common stock, \$0.001 par value (the “Common Stock”) and, (ii) one (1) detachable warrant (the “Warrants”) to purchase one (1) share of our Common Stock at an exercise price of \$0.08 per share.

On August 25, 2016 and September 27, 2016 in conjunction with the 2016 Private Placement, the Company issued an aggregate of 22,766,667 and 5,533,334, respectively, shares of common stock for an aggregate purchase price of \$1,366,000 and \$332,000, respectively.

The Company, in connection with the 2016 Private Placement, issued to the investors an aggregate of 28,300,001 warrants (the “Class L Warrants”) to purchase shares of common stock at an exercise price of \$0.08 per share. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**9. Equity transactions (continued)**

Pursuant to the terms of a Registration Rights Agreement that the Company entered with the accredited investors in connection with the 2016 Private Placement, the Company is required to file a registration statement that covers the shares of Common Stock and the shares of common stock issuable upon exercise of the Warrants. The failure on the part of the Company to satisfy certain deadlines described in the Registration Rights Agreement may subject the Company to payment of certain monetary penalties.

Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Private Placement of \$75,000. A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Private Placement of \$60,000.

At the closing of the 2016 Private Placement, the Company paid West Park Capital, Inc., the placement agent for the equity offering, cash compensation of \$169,800 based on the gross proceeds of the private placement and 2,830,000 Class L Warrants.

**Consulting Agreement**

In August 2016, the Company entered into a consulting agreement for which the fee for the services performed was paid with Company common stock. The Company issued 435,392 shares of common stock to Vigere Capital LP under this agreement. The fair value of the common stock issued to the consultant, based upon the closing market price of the Company's common stock at the date the common stock was issued, was recorded as a non-cash general and administrative expense for the three months ended September 30, 2016.

**Convertible Debenture and Restricted Stock**

On July 29, 2016, the Company entered into a financing transaction for the sale of a Convertible Debenture (the “Debenture”) in the principal amount of \$200,000, with gross proceeds of \$175,000 to the Company after payment of a 10% original issue discount. The offering was conducted pursuant to the exemption from registration provided by Section 4(a)(2) of the Act and Rule 506 of Regulation D thereunder. The Company did not utilize any form of general solicitation or general advertising in connection with the offering. The Debenture was offered and sold to one accredited investor (the “Investor”).

The Investor is entitled to, at any time or from time to time, commencing on the date that is one hundred fifty one (151) days from the Issuance Date set forth above convert the Conversion Amount into Conversion Shares, at a conversion price for each share of Common Stock equal to either (i) if the Company is Deposit/Withdrawal at Custodian (“DWAC”) Operational at the time of conversion, Seventy percent (70%) of the lowest closing bid price (as reported by Bloomberg LP) of Common Stock for the twenty (20) Trading Days immediately preceding the date of the date of conversion of the Debentures, or (ii) if either the Company is not DWAC Operational or the Common Stock is traded on the bottom tier OTC Pink (or, “pink sheets”) at the time of conversion, Sixty Five percent (65%) of the lowest closing bid price (as reported by Bloomberg LP) of the Common Stock for the twenty (20) Trading Days immediately preceding the date of conversion of the Debentures, subject in each case to equitable adjustments resulting from any stock splits, stock dividends, recapitalizations or similar events.

The Company recorded \$124,900 in interest expense for the beneficial conversion feature of the debenture.

The Debenture is secured by the accounts receivable of the Company and, unless earlier redeemed, matures on the third anniversary date of issuance. The Company paid a commitment fee of \$2,500 and issued 835,000 shares of Restricted Stock. The fair value of the Restricted Stock on the date of issuance was \$0.06 and \$50,100 was recorded as interest expense.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**9. Equity transactions (continued)**

In September 2016, the Company repaid the Debenture in full which totaled \$210,000 with a Redemption Price of 105% of the sum of the Principal Amount per the agreement. The premium of \$10,000 paid upon redemption was recorded as interest expense.

**2016 Equity Offering**

On March 11, 2016, April 6, 2016, and April 15, 2016 in conjunction with an equity offering of securities (the “2016 Equity Offering”) with select accredited investors, the Company issued an aggregate of 25,495,835, 3,083,334 and 1,437,501, respectively, shares of common stock for an aggregate purchase price of \$1,529,750, \$185,000, and \$86,200, respectively. The mandatory prepayment of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company was waived by HealthTronics, Inc. for this 2016 Equity Offering.

The Company, in connection with the 2016 Equity Offering, issued to the investors an aggregate of 30,016,670 warrants (the “Class L Warrants”) to purchase shares of common stock at an exercise price of \$0.08 per share. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019.

Pursuant to the terms of a Registration Rights Agreement that the Company entered into with the investors in connection with the 2016 Equity Offering, the Company is required to file a registration statement that covers the shares of common stock and the shares of common stock issuable upon exercise of the Class L Warrants. The registration statement was declared effective by the SEC on February 16, 2016.

Michael N. Nemelka, the brother of a member of the Company’s board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Equity Offering of \$100,000. A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Equity Offering of \$75,000.

At the closing of the 2016 Equity Offering, the Company paid Newport Coast Securities, Inc., the placement agent for the equity offering, cash compensation of \$180,095 based on the gross proceeds of the private placement and 3,001,667 Class L Warrants. In addition, the Company paid an escrow fee of \$4,000 and an attorney fee of \$20,000 from the gross proceeds.

**Series A Warrant Conversion**

On January 13, 2016, the Company entered into an Exchange Agreement (the “Exchange Agreement”) with certain beneficial owners (the “Investors”) of Series A warrants (the “Warrants”) to purchase shares of the Company’s common stock, \$0.001 par value per share (the “Common Stock”), pursuant to which the Investors exchanged (the “Exchange”) all of their respective Warrants for either (i) shares of Common Stock or (ii) shares of Common Stock and shares of the Company’s Series B Convertible Preferred Stock, \$0.001 par value (the “Preferred Stock”).

The Exchange was based on the following exchange ratio (the “Exchange Ratio”): 1 Series A Warrant = 0.4685 shares of capital stock. Investors who, as a result of the Exchange, owned in excess of 9.99% (the “Ownership Threshold”) of the outstanding Common Stock, received a mixture of Common Stock and shares of Preferred Stock. They received Common Stock up to the Ownership Threshold, and received shares of Preferred Stock beyond the Ownership Threshold (but the total shares of Common Stock and Preferred Stock issued to such holders was still based on the same Exchange Ratio). The relative rights, preferences, privileges and limitations of the Preferred Stock are as set forth in the Company’s Certificate of Designation of Series B Convertible Preferred Stock, which was filed with the Secretary of State of the State of Nevada on January 12, 2016 (the “Series B Certificate of Designation”).

## **SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

### **NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

#### **9. Equity transactions (continued)**

In the Exchange an aggregate number of 23,701,428 Warrants were exchanged for 7,447,954 shares of Common Stock and 293 shares of Preferred Stock. Pursuant to the Series B Certificate of Designation, each of the Preferred Stock shares is convertible into shares of Common Stock at an initial rate of 1 Preferred Stock share for 12,500 Common Stock shares, which conversion rate is subject to further adjustment as set forth in the Series B Certificate of Designation. Pursuant to the terms of the Series B Certificate of Designation, the holders of the Preferred Stock shares will generally be entitled to that number of votes as is equal to the number of shares of Common Stock into which the Preferred Stock may be converted as of the record date of such vote or consent, subject to the Beneficial Ownership Limitation.

In connection with entering into the Exchange Agreement, the Company also entered into a Registration Rights Agreement, dated January 13, 2016, with the Investors. The Registration Rights Agreement requires that the Company file with the SEC a registration statement to register for resale the shares of the Common Stock issued in connection with the Exchange and the Common Stock issuable upon conversion of the Preferred Stock shares (the "Preferred Stock Conversion Shares"). The registration statement was declared effective by the SEC on February 16, 2016.

#### **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 January 12, 2016, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series B 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 293 shares of preferred stock, par value \$0.001 per share, as Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock has a stated value of \$1,000 per share. On January 13, 2016, in connection with the Series A Warrant Conversion, the Company issued 293 shares of Series B Convertible Preferred Stock (for a more detailed discussion regarding the Series A Warrant Conversion, see Note 9).

Under the Certificate of Designation, holders of Series B 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 B 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 B 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 B Convertible Preferred Stock eligible for conversion without exceeding the Beneficial Ownership Limitation.

On April 29, 2016, the holders of Series B Convertible Preferred Stock converted the outstanding 293 shares of Series B Convertible Preferred Stock into 3,657,278 shares of common stock. As of April 29, 2016, there were no outstanding shares of Series B Convertible Preferred Stock.

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 a Private Placement, the Company issued 6,175 shares of Series A Convertible Preferred Stock. As of January 6, 2015 there were no outstanding shares of Series A Convertible Preferred Stock.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2017****11. Warrants**

A summary of the warrant activity as of March 31, 2017 and December 31, 2016, and the changes during the three months ended March 31, 2017, is presented as follows:

Warrant class	Outstanding as of December 31, 2016	Issued	Exercised	Converted	Expired	Outstanding as of March 31, 2017
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 K Warrants	5,200,000	-	-	-	-	5,200,000
Class L Warrants	65,945,005	-	(1,546,666)	-	-	64,398,339
Series A Warrants	2,106,594	-	(420,000 )	-	-	1,686,594
	78,086,749	-	(1,966,666)	-	-	76,120,083

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

	Exercise price/share	Expiration date
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 K Warrants	\$ 0.08	June 2025
Class L Warrants	\$ 0.08	March 2019
Series A Warrants	\$ 0.0334	March 2019

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 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 certain securities at a price lower than the then applicable exercise price of the warrants. The exercise price of the Series A Warrants was adjusted to \$0.0334 due to the 2016 Equity Offering (see Note 9). The 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.

In February 2013, the Company issued 2,000,000 warrants to a consultant to purchase the Company's common stock at \$0.35 per share (the "Class F Warrants"). The five year Class F Warrants vest 300,000 on the date of grant and 1,700,000 upon the completion of a \$5,000,000, or greater, capital raise on or prior to June 8, 2013. A capital raise was not completed for the requisite amount and the 1,700,000 Class F Warrants expired by their terms. The Company recorded the underlying cost of the 300,000 Class F Warrants as a cost of the Public Offering.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**11. Warrants (continued)**

In June 2015, the Company, in connection with the Note Amendment (Note 6), issued to HealthTronics, Inc. an aggregate total of 3,310,000 Class K Warrants to purchase shares of the Company's common stock, \$0.001 par value, 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.

In June 2016, the Company, in connection with the Second Amendment (Note 6), issued to HealthTronics, Inc., an additional 1,890,000 Class K Warrants to purchase shares of the Company's Common Stock at an exercise price of \$0.08 per share, subject to certain anti-dilution protection. The exercise price of the 3,310,000 Class K Warrants issued on June 15, 2015 was decreased to \$0.08 per share. The warrants vested upon issuance and expire after ten years.

The Class K Warrants, the Series A Warrants and the Series B Warrants are derivative financial instruments. The estimated fair value of the Class K Warrants at the date of grant was \$36,989 and recorded as debt discount, which is 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.

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A summary of the changes in the warrant liability as of March 31, 2017 and December 31, 2016, and the changes during the three months ended March 31, 2017, is presented as follows:

	Class K Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2016	\$884,000	\$358,120	\$1,242,120
Issued	-	-	-
Warrant redemption	-	(57,372 )	(57,372 )
Change in fair value	(208,000)	(115,223)	(323,223 )
Warrant liability as of March 31, 2017	\$676,000	\$185,525	\$861,525

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**12. Commitments and contingencies**

**Operating Leases**

Rent expense for the three months ended March 31, 2017 and 2016, was \$33,107 and \$42,519, respectively. Minimum future lease payments under the operating lease consist of the following:

<u>Year ending December 31,</u>	Amount
Remainder of 2017	\$99,220
2018	135,704
2019	139,775
2020	143,969
2021	148,288
Total	\$666,956

**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 three 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 March 31, 2017 and December 31, 2016, the Stock Incentive Plan reserved 22,500,000 shares of common stock for grant.

On November 9, 2016, the Company granted to the active employees, members of the board of directors and two members of the Company's Medical Advisory Board options to purchase 2,830,000 shares each of the Company's common stock at an exercise price of \$0.18 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of \$0.1524 resulting in compensation expense of \$431,292. Compensation cost was recognized upon grant.

On June 16, 2016, the Company granted to the active employees, members of the board of directors and two members of the Company's Medical Advisory Board options to purchase 3,300,000 shares each of the Company's common stock at an exercise price of \$0.04 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of \$0.0335 resulting in compensation expense of \$110,550. Compensation cost was recognized upon grant.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2017****13. Stock-based compensation (continued)**

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 year ended December 31, 2016:

	2016
Weighted average expected life in years	5.0
Weighted average risk free interest rate	1.10 %
Weighted average volatility	140.0%
Forfeiture rate	0.0 %
Expected dividend yield	0.0 %

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, \$0 and \$4,500 for the three months ended March 31, 2017 and 2016, respectively.

A summary of option activity as of March 31, 2017 and December 31, 2016, and the changes during the three months ended March 31, 2017, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2016	16,203,385	\$ 0.38
Granted	-	\$ -
Exercised	-	\$ -
Cancelled	-	\$ -
Forfeited or expired	-	\$ -
Outstanding as of March 31, 2017	16,203,385	\$ 0.38

Exercisable 16,203,385 \$ 0.38

The range of exercise prices for options was \$0.04 to \$2.00 for options outstanding at March 31, 2017 and December 31, 2016, respectively. The aggregate intrinsic value for all vested and exercisable options was \$436,500 and \$702,500 at March 31, 2017 and December 31, 2016, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options was 5.67 and 5.88 years as of March 31, 2017 and December 31, 2016, respectively.

#### **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.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**14. Earnings (loss) per share (continued)**

As a result of the net loss for the three months ended March 31, 2017 and 2016, 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 92,323,468 shares and 62,332,963 shares at March 31, 2017 and 2016, respectively.

**15. Subsequent events**

**Warrant Exercise**

On April 3, 2017, the Company issued 100,000 shares of common stock upon the exercise of 100,000 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant Public Offering agreement. The Company received proceeds of \$8,000.

On April 25, 2017, the Company issued 100,000 shares of common stock upon the exercise of 100,000 Class L Warrants to purchase shares of stock for \$0.08 per share under the terms of the Class L Warrant Public Offering agreement. The Company received proceeds of \$8,000.



## **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, 2016 included in our Annual Report on Form 10-K, filed with the SEC on March 31, 2017.*

### **Overview**

We are a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shock waves 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 was subject to two double-blinded, randomized Phase III clinical studies. The results of these clinical studies were submitted to the U.S. Food and Drug Administration (FDA) in late July 2016, after our in-person meeting to discuss the submission strategy, for possible approval in the second half of 2017.

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 and Asia. 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;  
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 improving heart muscle performance.

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

### **Recent Developments**

The FDA granted approval of our Investigational Device Exemption (IDE) to conduct two double-blinded, randomized clinical trials utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers.

The dermaPACE system was evaluated using two studies under IDE G070103. The studies were designed as prospective, randomized, double-blind, parallel-group, sham-controlled, multi-center 24-week studies at 39 centers. A total of 336 subjects were enrolled and treated with either dermaPACE plus conventional therapy or conventional therapy (a.k.a. standard of care) alone. Conventional therapy included, but was not limited to, debridement, saline-moistened gauze, and pressure reducing footwear. The objective of the studies was to compare the safety and efficacy of the dermaPACE device to sham-control application. The prospectively defined primary efficacy endpoint for the dermaPACE studies was the incidence of complete wound closure at 12 weeks post-initial application of the dermaPACE system (active or sham). Complete wound closure was defined as skin re-epithelialization without drainage or dressing requirements, confirmed over two consecutive visits within 12-weeks. If the wound was considered closed for the first time at the 12 week visit, then the next visit was used to confirm closure. Investigators continued to follow subjects and evaluate wound closure through 24 weeks.

The dermaPACE device completed its initial Phase III, IDE clinical 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 patient enrollment for the second, supplemental clinical trial began in June 2013. We completed enrollment for the 130 patients in this second trial in November 2014 and suspended further enrollment at that time.

The only significant difference between the two studies was the number of applications of the dermaPACE device. Study one (DERM01; n=206) prescribed four (4) device applications/treatments over a two-week period, whereas, study two (DERM02; n=130) prescribed up to eight (8) device applications (4 within the first two weeks of randomization, and 1 treatment every two weeks thereafter up to a total of 8 treatments over a 10-week period). If the wound was determined closed by the PI during the treatment regimen, any further planned applications were not performed.

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm<sup>2</sup> and 16cm<sup>2</sup>, inclusive. Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 – Day 0), the first treatment was applied (either dermaPACE or Sham Control application). Applications with either dermaPACE or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

A total of 336 patients were enrolled in the dermaPACE studies at 37 sites. The patients in the studies were followed for a total of 24 weeks. The studies' 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, 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 ( $p=0.320$ ). There were 39 out of 172 (22.67%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 30 out of 164 (18.29%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, and in conjunction with the FDA agreement to analyze the efficacy analysis carried over the full 24 weeks of the study, 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 61 (35.47%) dermaPACE subjects achieving complete wound closure compared with 40 (24.39%) of sham-control subjects ( $p=0.027$ ). At the 24 week endpoint, the rate of wound closure in the dermaPACE® cohort was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023.

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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 ( $p < 0.05$ ).

The proportion of patients with wound closure indicate a statistically significant difference between the dermaPACE and the control group in the proportion of subjects with the target-ulcer not closed over the course of the study ( $p$ -value=0.0346). Approximately 25% of dermaPACE® subjects reached wound closure per the study definition by day 84 (week 12). The same percentage in the control group (25%) did not reach wound closure until day 112 (week 16). These data indicate that in addition to the proportion of subjects reaching wound closure being higher in the dermaPACE® group, subjects are also reaching wound closure at a faster rate when dermaPACE is applied. dermaPACE demonstrated superior results in the prevention of wound expansion ( $\geq 10\%$  increase in wound size), when compared to the control, over the course of the study at 12 weeks (18.0% versus 31.1%;  $p=0.005$ , respectively). Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 7.7% in the dermaPACE group compared with 11.6% 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 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.

In June 2015 we met with the FDA to discuss analysis strategy for the data for the supplemental clinical trial and for the combined data of the two studies. In addition to the original data analysis plan for wound closure at 12 weeks, we proposed to analyze wound closure data at time points beyond 12 weeks, up to and including 24 weeks as we had positive results in the first study of 206 patients completed in 2011 at the 20 week endpoint. The FDA agreed to the additional analyses and stressed that their review and eventual decision will be based upon the totality of the data, both for efficacy and safety.

In October 2015 after freezing and locking the data, we performed data analysis. At the 12 week endpoint a total of 39 out of 172 (22.7%) of dermaPACE patients had complete wound closure, compared to 30 out of 164 (18.3%) in the control group. As expected, there was no statistically significant difference in wound closure at the 12 week follow up between the dermaPACE and control group; however, in subsequent visits a trend towards significance was shown resulting in a significant difference by the 20 week endpoint that was maintained through the end of the study. At the 24 week endpoint, the rate of wound closure in the dermaPACE patients was 37.8% compared to 26.2% for the control group, resulting in a  $p$ -value of 0.023. Additionally, there were no serious or related adverse events associated with the dermaPACE treatment reported during the course of the two studies and there were no issues regarding the tolerability of the treatment.

In April 2016, we met with FDA to discuss the safety and efficacy results of the trial as well as to discuss various submission strategies. Specifically, we discussed the applicability of the dermaPACE device and the associated

clinical trial results in regard to FDA's *de novo* review process. We concluded the meeting by informing FDA that we intended to submit the results under the *de novo* process.

Working with MCRA, we submitted to FDA a *de novo* petition on July 23, 2016. Due to the strong safety profile of our device and the efficacy of the data showing statistical significance for wound closure for dermaPACE subjects at 20 weeks, we believe that the dermaPACE device should be considered for classification into Class II as there is no legally marketed predicate device and there is not an existing Class III classification regulation or one or more approved PMAs (which would have required a reclassification under Section 513(e) or (f)(3) of the FD&C Act). Should FDA determine that the criteria at section 513(a)(1)(A) of (B) of the FD&C Act are met, FDA will grant the *de novo* petition, in which case dermaPACE will be classified as Class II and may be marketed immediately.

Finally, 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. The dermaPACE is also licensed for sale in Canada, Australia and New Zealand.

We are actively marketing the dermaPACE to the European Community, Canada and Asia/Pacific, utilizing distributors in select countries.

## **Financial Overview**

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At March 31, 2017, we had cash and cash equivalents totaling \$97,538. Management expects the cash used in operations for the Company during 2017 will be devoted to the commercialization of the dermaPACE, assuming FDA approval in 2017, and will continue to research and develop the non-medical uses of the product, both of which will require additional capital resources.

The continuation of our business is dependent upon raising additional capital during the second quarter of 2017 to fund operations. Management's plans are to obtain additional capital in 2017 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

Since our inception, we have incurred losses from operations each year. As of March 31, 2017, we had an accumulated deficit of \$99,926,980. 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 incur expenses related to seeking FDA approval for our dermaPACE device and then commercialization of the product when approval is received. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing, as discussed above, will provide the necessary funding for us to continue as a going concern for the next year.

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, 2016, filed with the SEC on March 31, 2017.

### **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, and the estimated fair value of stock-based compensation. 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, 2016, filed with the SEC on March 31, 2017, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, liabilities related to warrants issued, 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, research collaborators 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 and collaborators, 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 net realizable value, 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.

***Liabilities related to Warrants Issued***

We record certain common stock warrants we issued at fair value and recognize the change in the fair value of such warrants as a gain or loss, which we report in the Other Income (Expense) section in our Condensed Consolidated Statements of Comprehensive Loss. We report the warrants that we record at fair value as liabilities because they contain certain down-round provisions allowing for reduction of their exercise price. We estimate the fair value of these warrants using a binomial options pricing model.

### ***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 March 31, 2017 and 2016 (Unaudited)**

### ***Revenues and Cost of Revenues***

Revenues for the three months ended March 31, 2017 were \$149,569, compared to \$269,324 for the same period in 2016, a decrease of \$119,755, or 44%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The decrease in revenues for 2017 was due to lower sales of new orthoPACE devices and applicators, lower applicator refurbishments and lower wound kit sales in Europe and Asia/Pacific in 2017. There were two new and two clinical devices and four new applicators sold in 2017 and four new devices and twenty new applicators sold in 2016.

Cost of revenues for the three months ended March 31, 2017 were \$55,144, compared to \$73,181 for the same period in 2016. Gross profit as a percentage of revenues was 63% for the three months ended March 31, 2017, compared to 73% for the same period in 2016. The decrease in gross profit as a percentage of revenues in 2017 was due to sale of two clinical devices in 2017 (as compared to no such sales in 2016), which devices have a lower gross margin.

#### *Research and Development Expenses*

Research and development expenses for the three months ended March 31, 2017 were \$260,338, compared to \$309,955 for the same period in 2016, a decrease of \$49,617, or 16%. 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 2017 as a result of lower payments to consultants related to the *de novo* petition submission to the FDA in July 2016.

*General and Administrative Expenses*

General and administrative expenses for the three months ended March 31, 2017 were \$448,606, as compared to \$499,132 for the same period in 2016, a decrease of \$50,526, or 10%. The decrease in general and administrative expenses is due to reduced salary and related costs as a result of reduction in headcount in June 2016, lower rent expense due to move to new facility and lower travel expenses.

*Other Income (Expense)*

Other income (expense) was a net income of \$127,107 for the three months ended March 31, 2017, as compared to a net expense of \$1,035,107 for the same period in 2016, an increase in other income of \$1,162,214. The increase in other income for 2017 was due to gain on warrant valuation related to the lower stock price and loss on warrant conversion of \$888,419 recorded in 2016.

*Provision for Income Taxes*

At March 31, 2017, we had federal net operating loss carryforwards of \$73,775,701 through the year ended December 31, 2016 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 March 31, 2017 was \$493,532, or (\$0.00) per basic and diluted share, compared to a net loss of \$1,724,576, or (\$0.02) per basic and diluted share, for the same period in 2016, a decrease in the net loss of \$1,231,044, or 71%. The decrease in the net loss for 2017 was primarily due to the gain on the warrant valuation and lower operating expenses as noted above.

We anticipate that our operating losses will continue over the next few years as we await the decision of the FDA regarding our submission for the dermaPACE device for the treatment of diabetic foot ulcers but if we obtain FDA approval and are able to successfully commercialize, market and distribute the dermaPACE device, then we hope to partially or completely offset these losses within the next few years.

### **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 March 31, 2017, we had cash and cash equivalents totaling \$97,538. Management expects the cash used in operations for the Company during 2017 will be devoted to the commercialization of the dermaPACE, assuming FDA approval in 2017, and will continue to research and develop the non-medical uses of the product, both of which will require additional capital resources.

The continuation of our business is dependent upon raising additional capital during the second quarter of 2017 to fund operations. Management's plans are to obtain additional capital in 2017 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. 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. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

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

Cash and cash equivalents decreased by \$36,033 for the three months ended March 31, 2017 and increased by \$451,205 for the three months ended March 31, 2016. For the three months ended March 31, 2017 and 2016, net cash used by operating activities was \$114,884 and \$1,011,542, 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 three months ended March 31, 2017, as compared to the same period for 2016, of \$896,658, or 89%, was primarily due to the decreased operating expenses and increased payables in 2017. Net cash provided by financing activities for the three months ended March 31, 2017 was \$77,066 from the exercise of warrants. Net cash provided by financing activities for the three months ended March 31, 2016 was \$1,458,775, which consisted of the net proceeds from the 2016 Public Offering of \$1,352,775 and proceeds of \$106,000 from issuance of convertible promissory notes.

### **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, 2016, as filed with the SEC on March 31, 2017.

### **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**

Due to the fact that 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 required under Regulation S-K for “smaller reporting companies”.

### **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 Chief Financial Officer (principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2017. Based on this evaluation, the Acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2017.

### **Changes in Internal Control over Financial Reporting**

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

## **PART II — OTHER INFORMATION**

### **Item 6. EXHIBITS**

#### Exhibit No. Description

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.

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**SIGNATURES**

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

SANUWAVE HEALTH, INC.

Dated: May 15, 2017

By: */s/ Kevin A. Richardson, II*  
Name: Kevin A. Richardson, II  
Title: 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:

<b>Signatures</b>	<b>Capacity</b>	<b>Date</b>
By: <i>/s/ Kevin A. Richardson, II</i> Name: Kevin A. Richardson, II	Acting Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	May 15, 2017
By: <i>/s/ Lisa E. Sundstrom</i> Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	May 15, 2017
By: <i>/s/ John F. Nemelka</i> Name: John F. Nemelka	Director	May 15, 2017
By: <i>/s/ Alan L. Rubino</i> Name: Alan L. Rubino	Director	May 15, 2017

By: /s/ A. Michael Stolarski Director May 15, 2017  
Name: A. Michael Stolarski

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**EXHIBIT INDEX**

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