SANUWAVE Health, Inc.
Form 10-Q
November 14, 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 September 30, 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)

Nevada	20-1176000
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3360 Martin Farm Road, Suite 100 Suwanee, GA	30024
(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 November 10, 2017, there were issued and outstanding 139,249,926 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

Item1. FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$40,226	$133,571
Accounts receivable, net of allowance for doubtful accounts of $123,026 in 2017 and $35,196 in 2016	172,119	460,799
Inventory, net	176,109	231,953
Prepaid expenses	103,539	87,823
TOTAL CURRENT ASSETS	491,993	914,146
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4)	59,395	76,938
OTHER ASSETS	13,922	13,786
TOTAL ASSETS	$565,310	$1,004,870
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$1,435,431	$712,964
Accrued expenses (Note 5)	459,735	375,088
Accrued employee compensation	65,154	64,860
Advances from related parties and accredited investors (Note 6)	751,616	-
Interest payable, related parties (Note 7)	535,125	109,426
Short term loan, net (Note 8)	100,000	47,440
Warrant liability (Note 12)	1,058,202	1,242,120
Notes payable, related parties, net (Note 7)	5,183,310	5,364,572
TOTAL LIABILITIES	9,588,573	7,916,470
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' DEFICIT		
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 11)	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 authorized; 293 shares issued and 0 shares outstanding in 2017 and 2016, respectively (Note 11)	-	-
PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,532 shares authorized; no shares issued and outstanding (Note 11)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 139,099,843 and 137,219,968 issued and outstanding in 2017 and 2016, respectively (Note 10)	139,100	137,220
ADDITIONAL PAID-IN CAPITAL	93,077,145	92,436,697
ACCUMULATED DEFICIT	(102,194,242)	(99,433,448)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(45,266)	(52,069)
TOTAL STOCKHOLDERS' DEFICIT	(9,023,263)	(6,911,600)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$565,310	$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 September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
REVENUES	$161,585	$255,652	$422,199	$728,382
COST OF REVENUES (exclusive of depreciation and amortization shown below)	61,684	98,678	141,523	249,847
OPERATING EXPENSES				
Research and development	266,837	266,473	965,084	1,052,595
General and administrative	475,377	645,863	1,875,891	1,734,891
Depreciation	5,465	1,554	17,543	3,227
Amortization	-	76,689	-	230,067
Gain on sale of property and equipment	-	-	-	(1,000)
TOTAL OPERATING EXPENSES	747,679	990,579	2,858,518	3,019,780
OPERATING LOSS	(647,778)	(833,605)	(2,577,842)	(2,541,245)
OTHER INCOME (EXPENSE)				
(Loss) Gain on warrant valuation adjustment and conversion	(41,681)	(43,536)	316,952	(812,983)
Interest expense, net	(160,978)	(259,302)	(496,997)	(623,066)
Loss on foreign currency exchange	(888)	(3,367)	(2,907)	(9,215)
TOTAL OTHER INCOME (EXPENSE), NET	(203,547)	(306,205)	(182,952)	(1,445,264)
NET LOSS	(851,325)	(1,139,810)	(2,760,794)	(3,986,509)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	20,570	(2,268)	6,803	(4,980)
TOTAL COMPREHENSIVE LOSS	$(830,755)	$(1,142,078)	$(2,753,991)	$(3,991,489)
LOSS PER SHARE:				
Net loss - basic and diluted	$(0.01)	$(0.01)	$(0.02)	$(0.04)

Weighted average shares outstanding - basic and diluted	139,099,843	115,528,604	138,711,527	97,798,261

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

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

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(2,760,794)	$(3,986,509)
Adjustments to reconcile net loss to net cash used by operating activities to net cash used by operating activities		
Depreciation	17,543	3,227
Change in allowance for doubtful accounts	87,830	15,376
Amortization	-	230,067
Stock-based compensation - employees, directors and advisors	482,295	116,550
(Gain) Loss on warrant valuation adjustment	(316,952)	812,982
Amortization of debt discount	71,298	18,548
Amortization of debt issuance costs	-	114,522
Loss on conversion option of promissory note payable	-	75,422
Loss on conversion option of convertible debenture	-	50,100
Stock issued for consulting services	-	43,540
Gain on sale of property and equipment	-	(1,000)
Changes in assets - (increase)/decrease		
Accounts receivable - trade	200,850	(82,219)
Inventory	55,844	17,922
Prepaid expenses	(15,716)	755
Other	(136)	(2,843)
Changes in liabilities - increase/(decrease)		
Accounts payable	722,467	(133,173)
Accrued expenses	84,647	60,369
Accrued employee compensation	294	209,465
Interest payable, related parties	425,699	(239,803)
Promissory notes, accrued interest	-	(32,271)
NET CASH USED BY OPERATING ACTIVITIES	(944,831)	(2,708,973)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of property and equipment	-	1,000

Purchases of property and equipment	-	(7,878)
NET CASH USED BY INVESTING ACTIVITIES	-	(6,878)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from warrant exercise	93,067	32,000
Advances from related parties and accredited investors	751,616	-
Proceeds from 2016 Public Offering, net	-	1,596,855
Proceeds from 2016 Private Offering, net	-	1,528,200
Proceeds from convertible promissory notes, net	-	106,000
Proceeds from convertible debenture, net	-	175,000
Payment of convertible promissory notes	-	(155,750)
Payment of convertible debenture	-	(210,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	844,683	3,072,305
EFFECT OF EXCHANGE RATES ON CASH	6,803	(4,980)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(93,345)	351,474
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	133,571	152,930
CASH AND CASH EQUIVALENTS, END OF PERIOD	$40,226	$504,404
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$-	$630,549
NONCASH INVESTING ACTIVITIES		
Cashless warrant conversion	$66,966	$-

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

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

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 thirdfourth quarter of 2017. As of September 30, 2017, the Company had an accumulated deficit of $102,194,242 and cash and cash equivalents of $40,226. For the nine months ended September 30, 2017 and 2016, the net cash used by operating activities was $944,831 and $2,708,973, respectively. The Company incurred a net loss of $2,760,794 for the nine months ended September 30, 2017 and a net loss of $6,439,040 for the year ended December 31, 2016. The operating losses and the Events of Default on the Notes payable, related parties (see Note 7) 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 fourth 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 September 30, 2017 and for the three and nine months ended September 30, 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 and nine month periods ended September 30, 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
September 30, 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 2018 instead of the current effective date, which was the first quarter of fiscal 2017. This one year deferral was issued by the FASB in ASU 2015-14, Revenue from Contracts with Customers (Topic 606.). 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 will adopt the standard effective January 1, 2018 and currently anticipates using the retrospective approach with the cumulative effect of initially adopting the new accounting standard at the date of adoption. The Company has completed a high-level impact assessment and has commenced an in-depth evaluation of the adoption impact, which involves the review of pre-existing customer contracts and arrangements. The Company is still in the process of evaluating the impact that the pending adoption of the new standard will have on these contracts and transactions. The new standard will require the Company to include expanded qualitative and quantitative disclosures relating to the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers, including specific judgments and estimates used by management.

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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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3. Summary of Significant Accounting Policies (continued)

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.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480): Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this ASU addresses the complexity and reporting burden associated with the accounting for freestanding and embedded instruments with down round features as liabilities subject to fair value measurement. Part II of this ASU addresses the difficulty of navigating Topic 480. Part I of this ASU will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for an entity in an interim or annual period. 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.

4. Property and equipment

Property and equipment consists of the following:

	September 30, 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	(472,770)	(455,227)
Net property and equipment	$59,395	$76,938

Depreciation expense was $5,465 and $1,554 for the three months ended September 30, 2017 and 2016, respectively and $17,543 and $3,227 for the nine months ended September 30, 2017 and 2016, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2017

5. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2017	December 31, 2016
Accrued executive severance	$100,000	$100,000
Accrued board of director's fees	95,000	16,000
Accrued audit and tax preparation	83,095	100,000
Accrued outside services	53,912	31,533
Deferred rent	44,594	41,341
Accrued clinical expenses	23,650	13,650
Deferred revenue	21,060	18,810
Accrued travel and entertainment	20,000	-
Accrued legal professional fees	13,609	45,000
Accrued other	4,815	8,754
Total Accrued expenses	$459,735	$375,088

6. Advances from related parties

The Company has received cash advances from related parties and accredited investors to help fund the Company's operations. These advances are a part of a subscription agreement that the Company is offering to issue convertible promissory notes. As of September 30, 2017, the Company had received $751,616 from related parties and accredited investors.

10% Convertible Promissory Notes

On March 27, 2017, the Company began offering subscriptions for 10% convertible promissory notes (the "10% Convertible Promissory Notes") to selected accredited investors. Up to $2,500,000 aggregate principal amount of 10% Convertible Promissory Notes are being offered by the Company. The Company is currently working on completing this offering.

The 10% Convertible Promissory Notes have a six month term from the subscription date and the note holders can convert the 10% Convertible Promissory Notes at any time during the term to the number of shares of Common Stock equal to the amount obtained by dividing (i) the amount of unpaid principal and accrued interest on the note by (ii) $0.11. The 10% Convertible Promissory Notes include a warrant agreement (the "Class N Warrant Agreement") to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount, by (ii) $0.11. The Class N Warrant Agreement expires March 17, 2019.

On November 3, 2017, the Company issued $1,124,440 in 10% Convertible Promissory Notes to related parties and accredited investors and issued 10,222,180 Class N Warrants. The fair value of the Class N Warrants will be calculated and recorded in November 2017. On November 3, 2017, Premier Shockwave Inc., a company owned by Anthony Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, purchased $330,000 of the 10% Convertible Promissory Notes and was issued 3,000,000 Class N Warrants.

The Company, the related parties and the accredited investors are executing and delivering the 10% Convertible Promissory Notes and the Class N Warrants in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D ("Regulation D").

Pursuant to the terms of a Registration Rights Agreement that the Company entered with the accredited investors in connection with the 10% Convertible Promissory Note, the Company is required to file a registration statement that covers the shares of Common Stock issuable upon conversion of the 10% Convertible Promissory Notes or upon exercise of the Class N 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.

7. Notes payable, related parties

The notes payable, related parties were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. The notes payable, related parties bore interest at 6% per annum. Quarterly interest through June 30, 2010 was accrued and added to the principal balance. Interest was paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal was due August 1, 2015.

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. Events of Default under the notes payable, related parties have occurred and are continuing on account of the failure of SANUWAVE, Inc., a Delaware corporation, a wholly owned subsidiary of the Company and the borrower under the notes payable, related parties, to make the required payments of interest which were due on December 31, 2016, March 31, 2017, June 30, 2017, and September 30, 2017 (collectively, the "Defaults"). As a result of the Defaults, the notes payable, related parties have been accruing interest at the rate of 10% per annum since January 12, 2017 and continue to accrue interest at such rate. 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2017

7. Notes payable, related parties (continued)

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.

On August 3, 2017, the Company and HealthTronics, Inc. entered into a third amendment (the "Third Amendment") to amend certain provisions of the notes payable, related parties. The Third Amendment provides for the extension of the due date to December 31, 2018 and revision of the mandatory prepayment provisions.

The notes payable, related parties had an aggregate net outstanding principal balance of $5,183,310, net of $189,433 debt discount, at September 30, 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 per warrant 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 per warrant and $9,214 was recorded as a debt discount to be amortized over the life of the amendment.

In addition, the Company, in connection with the Third Amendment, issued to HealthTronics, Inc. on August 3, 2017, an additional 2,000,000 Class K Warrants to purchase shares of the Company's Common Stock at an exercise price of $0.11 per share, subject to certain anti-dilution protection. The fair value of these warrants on the date of issuance was $0.10 per warrant and $200,000 was recorded as a debt discount to be amortized over the life of the amendment.

Accrued interest currently payable totaled $535,125 and $109,426 at September 30, 2017 and December 31, 2016, respectively. Interest expense on notes payable, related parties totaled $160,979 and $129,808 for the three months ended September 30, 2017 and 2016, respectively, and $444,437 and $390,746 for the nine months ended September 30, 2017 and 2016, respectively.

8. 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 the date that substantial money is obtained from the Company's Korean distributor or date that money is obtained from a new distributor. This short term note is currently in default.

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 the yet to be issued warrants on the date of issuance of the short term loan was $0.1168 per warrant, 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.

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9. 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 2014.

At September 30, 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 NOLs, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, Income Taxes, the Company's management believes that there is not sufficient evidence at September 30, 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.

10. Equity transactions

Warrant Exercise

In April 2017, the Company issued 200,000 shares of common stock upon the exercise of 200,000 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 $16,000.

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 $29,067.

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 June 22, 2017, the Company issued 84,514 shares of common stock to Arthur Motch III upon the cashless exercise of 125,246 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.1027 per share as determined under the terms of the Series A Warrant agreement.

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10. Equity transactions (continued)

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.

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 Securities and Exchange 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 Common Stock and, (ii)

one (1) detachable warrant (the “Warrants”) to purchase one (1) share of 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.

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10. Equity transactions (continued)

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.

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 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 Common Stock at the date the Common Stock was issued, was recorded as a non-cash general and administrative expense in the amount of $43,539 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 in December 2016.

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10. Equity transactions (continued)

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 in July 2016.

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 in September 2016.

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 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”).

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10. Equity transactions (continued)

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").

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.

11. 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 10).

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.

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11. Preferred Stock (continued)

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.

12. Warrants

A summary of the warrant activity as of September 30, 2017 and December 31, 2016, and the changes during the nine months ended September 30, 2017, is presented as follows:

Warrant class	Outstanding as of December 31, 2016	Issued	Exercised	Converted	Expired	Outstanding as of September 30, 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	2,000,000	-	-	-	7,200,000
Class L Warrants	65,945,005	-	(1,746,666)	-	-	64,198,339
Series A Warrants	2,106,594	-	(545,246)	-	-	1,561,348
	78,086,749	2,000,000	(2,291,912)	-	-	77,794,837

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 K Warrants	$ 0.11	August 2027
Class L Warrants	$ 0.08	March 2019
Series A Warrants	$ 0.03	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.

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12. Warrants (continued)

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 Note10). 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.

In June 2015, the Company, in connection with the Note Amendment (see Note 7), 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 (see Note 7), 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.

In August 2017, the Company, in connection with the Third Amendment (see Note 7), issued to HealthTronics, Inc., an additional 2,000,000 Class K Warrants to purchase shares of the Company's Common Stock at an exercise price of $0.11 per share, subject to certain anti-dilution protection. 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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12. Warrants (continued)

A summary of the changes in the warrant liability as of September 30, 2017 and December 31, 2016, and the changes during the three and nine months ended September 30, 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
Issued	-	-	-
Warrant redemption	-	(9,594)	(9,594)
Change in fair value	-	(35,410)	(35,410)
Warrant liability as of June 30, 2017	$676,000	$140,521	$816,521
Issued	200,000	-	200,000
Warrant redemption	-	-	-
Change in fair value	(52,000)	93,681	41,681
Warrant liability as of September 30, 2017	$824,000	$234,202	$1,058,202

13. Commitments and contingencies

Operating Leases

Rent expense for the three months ended September 30, 2017 and 2016, was $33,572 and $47,108, respectively and for the nine months ended September 30, 2017 and 2016 was $99,800 and $130,083, respectively. Minimum future lease payments under the operating lease consist of the following:

Year ending December 31,	Amount
Remainder of 2017	$33,507
2018	135,704
2019	139,775

2020	143,969
2021	148,288
Total	$601,243

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.

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14. 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 September 30, 2017 and December 31, 2016, the Stock Incentive Plan reserved 22,500,000 shares of common stock for grant.

On June 15, 2017, the Company granted to the active employees, members of the board of directors and members of the Company's Medical Advisory Board options to purchase 5,550,000 shares each of the Company's common stock at an exercise price of $0.11 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 $0.0869 resulting in compensation expense of $482,295. Compensation cost was recognized upon 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.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the nine months ended September 30, 2017 and the year ended December 31, 2016:

	2017	2016
Weighted average expected life in years	5.0	5.0
Weighted average risk free interest rate	1.76%	1.28%
Weighted average volatility	120.0%	133.54%
Forfeiture rate	0.0%	0.0%
Expected dividend yield	0.0%	0.0%

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, $0 for each of the three months ended September 30, 2017 and 2016, and $482,295 and $116,550 for the nine months ended September 30, 2017 and 2016, respectively.

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14. Stock-based compensation (continued)

A summary of option activity as of September 30, 2017 and December 31, 2016, and the changes during the three and nine months ended September 30, 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
Granted	5,550,000	$0.11
Exercised	-	$-
Cancelled	-	$-
Forfeited or expired	(160,000)	$0.22
Outstanding as of June 30, 2017	21,593,385	$0.31
Granted	-	$-
Exercised	-	$-
Cancelled	-	$-
Forfeited or expired	-	$-
Outstanding as of September 30, 2017	21,593,385	$0.31
Exercisable	21,593,385	$0.31

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at September 30, 2017 and December 31, 2016, respectively. The aggregate intrinsic value for all vested and exercisable options was $1,027,516 and $702,500 at September 30, 2017 and December 31, 2016, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options was 7.62 and 5.88 years as of September 30, 2017 and December 31, 2016, respectively.

15. Earnings (loss) per share

The Company calculates net income (loss) per share in accordance with ASC 260, Earnings Per Share. Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. To the extent that securities are “anti-dilutive,” they are excluded from the calculation of diluted net income (loss) per share.

As a result of the net loss for the three and nine months ended September 30, 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 99,388,222 shares and 92,046,867 shares at September 30, 2017 and 2016, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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16. Subsequent events

Brazil Joint Venture

On September 27, 2017, we entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), effective as of September 25, 2017, for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed will pay the Company an initial partnership fee, with monthly partnership fees payable thereafter over the following eighteen months. Profits from the joint venture are distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial partnership fee was received on October 6, 2017.

Cashless Warrant Exercise

On October 24, 2017, the Company issued 150,083 shares of common stock upon the cashless exercise of 300,166 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.16 per share as determined under the terms of the Class L Warrant Private Offering agreement.

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 fourth quarter of 2017 or first quarter of 2018.

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

On September 27, 2017, we entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), effective as of September 25, 2017, for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed will pay the Company an initial partnership fee, with monthly partnership fees payable thereafter over the following eighteen months. Profits from the joint venture are distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial partnership fee was received on October 6, 2017.

Clinical Trials and Marketing

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 1cm2 and 16cm2, 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.

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 (≥ 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. 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 September 30, 2017, we had cash and cash equivalents totaling $40,226. 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 late 2017 or early 2018, 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 fourth 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 September 30, 2017, we had an accumulated deficit of $102,194,242. 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 September 30, 2017 and 2016 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended September 30, 2017 were $161,585, compared to $255,652 for the same period in 2016, a decrease of $94,067, or 37%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The decrease in revenues for 2017 was due to lower sales of new orthoPACE devices and refurbishment of applicators in Europe and Asia/Pacific in 2017.

Cost of revenues for the three months ended September 30, 2017 were $61,684, compared to $98,678 for the same period in 2016. Gross profit as a percentage of revenues was 62% for the three months ended September 30, 2017, compared to 61% for the same period in 2016. The increase in gross profit as a percentage of revenues in 2017 was due to sale of devices in 2016, which have a lower gross margin than new and refurbishment of applicators.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2017 were $266,837, compared to $266,473 for the same period in 2016, an increase of $364. 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.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2017 were $475,377, as compared to $645,863 for the same period in 2016, a decrease of $170,486, or 26%. The decrease in general and administrative expenses was due to lower legal fees, lower salary and benefits as a result of reduced headcount and decrease in bad debt reserve.

Other Income (Expense)

Other income (expense) was a net expense of $203,547 for the three months ended September 30, 2017, as compared to $306,205 for the same period in 2016, a decrease in other expense of $102,658 or 34%. The decrease in other expense for 2017 was due to lower interest expense related to promissory notes in 2016.

Provision for Income Taxes

At September 30, 2017, we had federal net operating loss carryforwards 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

Provision for Income Taxes

At September 30, 2017, we had federal net operating loss carryforwards 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 September 30, 2017 was $851,325, or ($0.01) per basic and diluted share, compared to a net loss of $1,139,810, or ($0.01) per basic and diluted share, for the same period in 2016, a decrease in the net loss of $288,485, or 25%. The decrease in the net loss for 2017 was primarily due to lower general and administrative expenses as noted above as well as reduction of amortization expense.

We anticipate that our operating losses will continue over the next few years as we continue to incur expenses related to seeking FDA approval for our dermaPACE device for the treatment of diabetic foot ulcers and then commercialization of the product when approval is received. If we obtain such FDA approval and are able to successfully commercialize, market and distribute the dermaPACE device, we hope to partially or completely offset these losses in the future.

Results of Operations for the Nine Months ended September 30, 2017 and 2016 (Unaudited)

Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2017 were $422,199, compared to $728,382 for the same period in 2016, a decrease of $306,183, or 42%. 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 and lower applicator refurbishments in Europe and Asia/Pacific in 2017.

Cost of revenues for the nine months ended September 30, 2017 were $141,523, compared to $249,847 for the same period in 2016. Gross profit as a percentage of revenues was 66% for the nine months ended September 30, 2017 and 2016.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2017 were $965,084, compared to $1,052,595 for the same period in 2016, a decrease of $87,511, or 8%. 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 nine months ended September 30, 2017 were $1,875,891, as compared to $1,734,891 for the same period in 2016, an increase of $141,000, or 8%. The increase in general and administrative expenses was due to non-cash stock compensation expense for stock options issued in June 2017 and increase in bad debt reserve which was partially offset by lower legal and investor relations fees.

Other Income (Expense)

Other income (expense) was a net expense of $182,952 for the nine months ended September 30, 2017, as compared to a net expense of $1,445,264 for the same period in 2016, a decrease in other expense of $1,262,312, or 87%. The decrease in other expense for 2017 was due to gain on warrant valuation and lower interest expense related to promissory notes in 2016.

Provision for Income Taxes

At September 30, 2017, we had federal net operating loss carryforwards 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

Provision for Income Taxes

At September 30, 2017, we had federal net operating loss carryforwards 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 nine months ended September 30, 2017 was $2,760,794, or ($0.02) per basic and diluted share, compared to a net loss of $3,986,509, or ($0.04) per basic and diluted share, for the same period in 2016, a decrease in the net loss of $1,225,715, or 31%. 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 continue to incur expenses related to seeking FDA approval for our dermaPACE device for the treatment of diabetic foot ulcers and then commercialization of the product when approval is received. If we obtain such FDA approval and are able to successfully commercialize, market and distribute the dermaPACE device, we hope to partially or completely offset

these losses in the future.

Liquidity and Capital Resources

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2017, we had cash and cash equivalents totaling $40,226. 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. At September 30, 2017, the Company's distributor in South Korea accounted for 78% of the total outstanding accounts receivable. Due to the political climate and uncertainty in South Korea, this distributor has not been able to finalize the expected sales in late 2016 and 2017 and therefore has been unable to pay the Company in a timely manner. The Company has accounted for 48% of their outstanding balance as a bad debt reserve as of September 30, 2017 and continues to work with the distributor on a payment plan to get the distributor's account current by December 31, 2017.

The continuation of our business is dependent upon raising additional capital during the fourth 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 we may be required to use some or all of the net proceeds to repay our indebtedness, 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 $93,345 for the nine months ended September 30, 2017 and increased by $351,474 for the nine months ended September 30, 2016. For the nine months ended September 30, 2017 and 2016, net cash used by operating activities was $944,831 and $2,708,973, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for the nine months ended September 30, 2017, as compared to the same period for 2016, of $1,764,142, or 65%, was primarily due to the decreased operating expenses and increased payables in 2017. Net cash provided by financing activities for the nine months ended September 30, 2017 was $93,067 from the exercise of warrants and $751,616 from the advances from related parties for subscription agreements to be executed in the fourth quarter. Net cash provided by financing activities for the nine months ended September 30, 2016 was $3,072,305, which consisted of the net proceeds from the 2016 Public Offering of $1,596,855, net proceeds from the 2016 Private Offering of $1,528,200 and proceeds of $32,000 from exercise of warrants and net payments of $84,750 of convertible debt.

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, related parties. 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 September 30, 2017. Based on this evaluation, the Acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not operating effectively as of September 30, 2017. Our disclosure controls and procedures were not effective because of the “material weakness” described below.

A “material weakness” is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis by the company’s internal controls. As a result of its review, management concluded that we had a material weakness in our internal control over financial reporting process for the lack of internal expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions related to complex financial instruments and derivatives.

Management believes the material weakness identified above was due to the complex and non-routine nature of the Company’s complex financial instruments and derivatives.

Management’s Plan to Remediate Material Weakness

Management has developed a remediation plan to address the material weakness related to its processes and procedures surrounding the accounting for complex financial instruments and derivatives. Implementation of the remediation plan is in review by the Board of Director’s and could consist of, among other things, redesigning the procedures to enhance its identification, capture, review, approval and recording of contractual terms included in contractual debt and equity arrangements. Management is also pursuing obtaining additional interpretive guidance on identifying and accounting for complex financial instruments and derivatives as well as engaging, as necessary, an outside consultant to assist in the application of United States GAAP to complex transactions, including the accounting for derivatives. These measures are intended both to address the identified material weakness and to enhance our overall internal control environment.

Changes in Internal Control over Financial Reporting

There have been 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. Management is in the process of designing changes to its controls as discussed above in Management's Plan to Remediate Material Weakness.

PART II — OTHER INFORMATION

Item 6. EXHIBITS

Exhibit No.	Description
4.1	Class K Warrant Agreement dated as of August 3, 2017, between SANUWAVE Health, Inc. and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
4.2	Form of Class N Warrant. (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
10.1	Third Amendment to promissory notes entered into as of August 3, 2017 by and among SANUWAVE Health, Inc., SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
10.2*#	Binding Term Sheet for Joint Venture Agreement between SANUWAVE Health, Inc. and MundiMed Distribuidora Hospitalar LTDA effective as of September 25, 2017.
10.3	Form of 10% Convertible Promissory Note, by and among the Company and the accredited investors a party thereto, dated November 3, 2017. (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
10.4	Form of Registration Rights Agreement, by and among the Company and the accredited investors a party thereto, dated November 3, 2017 (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
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.

* Filed herewith.

Confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and Submitted separately to the Securities and Exchange Commission.
† XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

SIGNATURES

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

SANUWAVE HEALTH, INC.

Dated: November 14, 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:

Signatures	Capacity	Date
By: /s/ Kevin A. Richardson, II Name: Kevin A. Richardson, II	Acting Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	November 14, 2017
By: /s/ Lisa E. Sundstrom Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	November 14, 2017