SANUWAVE Health, Inc.
Form 10-Q
August 15, 2016

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 June 30, 2016

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	(I.R.S. Employer
incorporation or organization)	Identification No.)
11475 Great Oaks Way, Suite 150	**30022**

Alpharetta, GA
(Address of principal executive offices) (Zip Code)

(770) 419-7525

(Registrant's telephone number, including area code)

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

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

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

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

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

As of August 10, 2016, there were issued and outstanding 105,013,421 shares of the registrant’s common stock, $0.001 par value.

SANUWAVE Health, Inc.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of SANUWAVE Health, Inc. and its subsidiaries (“SANUWAVE” or the “Company”) contains forward-looking statements. All statements in this Quarterly Report on Form 10-Q, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company’s future financial results, clinical trial results, regulatory approvals, operating results, business strategies, projected costs, products, competitive positions, management’s plans and objectives for future operations, and industry trends. These forward-looking statements are based on management’s estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” and “co negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission (the “SEC”), specifically the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 30, 2016 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, 2015, filed on March 30, 2016.

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

PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	June 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$122,948	$152,930
Accounts receivable, net of allowance for doubtful accounts of $14,576 in 2016 and $8,963 in 2015	97,154	74,454
Inventory	230,906	284,908
Prepaid expenses	97,823	123,988
TOTAL CURRENT ASSETS	548,831	636,280
PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation	2,555	4,228
OTHER ASSETS	11,141	11,097
INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 4)	153,378	306,756
TOTAL ASSETS	$715,905	$958,361
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$458,277	$509,266
Accrued expenses (Note 5)	295,823	359,374
Accrued employee compensation	408,939	241,542
Interest payable, related parties (Note 6)	108,224	239,803
Promissory notes payable (Note 7)	115,933	-
Warrant liability (Note 11)	119,900	138,100
TOTAL CURRENT LIABILITIES	1,507,096	1,488,085

NON-CURRENT LIABILITIES		
Notes payable, related parties (Note 6)	5,334,234	5,348,112
TOTAL LIABILITIES	6,841,330	6,836,197
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 authorized; 6,175 shares issued and 0 shares outstanding in 2016 and 2015 (Note 10)	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 authorized; 293 shares issued and 293 and 0 shares outstanding in 2016 and 2015, respectively (Note 10)	-	-
PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,532 shares authorized; no shares issued and outstanding (Note 10)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 104,178,421 and 63,056,519 issued and outstanding in 2016 and 2015, respectively (Note 9)	104,178	63,057
ADDITIONAL PAID-IN CAPITAL	89,647,379	87,086,677
ACCUMULATED DEFICIT	(95,841,107)	(92,994,408)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(35,875)	(33,162)
TOTAL STOCKHOLDERS' DEFICIT	(6,125,425)	(5,877,836)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$715,905	$958,361

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 June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
REVENUES	$203,406	$239,983	$472,730	$450,435
COST OF REVENUES	77,988	75,779	151,169	134,597
GROSS PROFIT	125,418	164,204	321,561	315,838
OPERATING EXPENSES				
Research and development	476,167	456,789	786,122	1,091,412
General and administrative	589,896	636,570	1,089,028	1,202,862
Depreciation	837	925	1,673	1,850
Amortization	76,689	76,689	153,378	153,378
TOTAL OPERATING EXPENSES	1,143,589	1,170,973	2,030,201	2,449,502
OPERATING LOSS	(1,018,171)	(1,006,769)	(1,708,640)	(2,133,664)
OTHER INCOME (EXPENSE)				
Gain on sale of assets	-	-	1,000	-
Gain(loss) on warrant valuation adjustment (Note 11)	28,250	(429,311)	(769,447)	(373,285)
Interest expense, net	(110,557)	(81,636)	(264,744)	(160,980)
Amortization of debt issuance costs	(12,999)	-	(87,548)	-
Amortization of debt discount	(5,778)	-	(11,472)	-
Loss on foreign currency exchange	(2,868)	(3,817)	(5,848)	(12,719)
TOTAL OTHER EXPENSE	(103,952)	(514,764)	(1,138,059)	(546,984)
NET LOSS	(1,122,123)	(1,521,533)	(2,846,699)	(2,680,648)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	(5,684)	(768)	(2,713)	(13,486)
TOTAL COMPREHENSIVE LOSS	$(1,127,807)	$(1,522,301)	$(2,849,412)	$(2,694,134)
LOSS PER SHARE:				
Net loss - basic and diluted	$(0.01)	$(0.02)	$(0.03)	$(0.04)

Weighted average shares outstanding - basic and diluted	102,645,697	63,056,519	88,933,089	62,993,885

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)

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(2,846,699)	$(2,680,648)
Adjustments to reconcile loss from continuing operations to net cash used by operating activities		
Amortization	153,378	153,378
Depreciation	1,673	1,850
Change in allowance for doubtful accounts	5,613	(3,099)
Stock-based compensation - employees, directors and advisors	116,550	50,062
Loss on warrant valuation adjustment	769,447	373,285
Loss on conversion option of promissory notes payable	75,422	-
Gain on sale of property and equipment	(1,000)	-
Amortization of debt issuance costs	87,548	-
Amortization of debt discount	11,472	951
Changes in assets - (increase)/decrease		
Accounts receivable - trade	(28,313)	40,995
Inventory	54,002	3,731
Prepaid expenses	26,165	(16,904)
Other	(44)	(180)
Changes in liabilities - increase/(decrease)		
Accounts payable	(50,989)	53,688
Accrued expenses	(63,551)	(19,654)
Accrued employee compensation	167,397	125,583
Interest payable, related parties	(131,579)	(896)
Promissory notes payable - accrued interest	(77,615)	-
NET CASH USED BY OPERATING ACTIVITIES	(1,731,124)	(1,917,858)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of property and equipment	1,000	-
NET CASH PROVIDED BY INVESTING ACTIVITIES	1,000	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from 2016 Equity Offering, net	1,596,855	-
Proceeds from convertible promissory notes, net	106,000	-

NET CASH PROVIDED BY FINANCING ACTIVITIES	1,702,855	-
EFFECT OF EXCHANGE RATES ON CASH	(2,713)	(13,486)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(29,982)	(1,931,344)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	152,930	3,547,071
CASH AND CASH EQUIVALENTS, END OF PERIOD	$122,948	$1,615,727
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$392,516	$161,936

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

June 30, 2016

1. Nature of the Business

SANUWAVE Health, Inc. and subsidiaries (the “Company”) is an acoustic pressure shock wave technology company using a patented system of noninvasive, high-energy, acoustic pressure shock waves for indications such as regenerative medicine and other applications. The Company’s initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of skin, musculoskeletal tissue 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. A *de novo* petition was sent to FDA on July 23, 2016 requesting Agency review and classification of the dermaPACE device for treating diabetic foot ulcers as a Class II device, for possible approval in late 2016 or early 2017.

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

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, for sterilizing food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

2. Going Concern

The Company does not currently generate significant recurring revenue and will require additional capital during the second and third quarter of 2016. As of June 30, 2016, the Company had an accumulated deficit of $95,841,107 and cash and cash equivalents of $122,948. For the six months ended June 30, 2016 and 2015, the net cash used by operating activities was $1,731,124 and $1,917,858, respectively. The Company incurred a net loss of $2,846,699 for the six months ended June 30, 2016 and a net loss of $4,810,285 for the year ended December 31, 2015. The operating losses create an uncertainty about the Company’s ability to continue as a going concern.

The continuation of the Company's business is dependent upon raising additional capital during the third quarter of 2016 to fund operations. Management's plans are to obtain additional capital in 2016 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

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 June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 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 six month periods ended June 30, 2016 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2016.

The condensed consolidated balance sheet at December 31, 2015 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, 2015, filed with the SEC on March 30, 2016.

Recently Issued Accounting Standards

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2019 instead of the current effective date, which was the first quarter of fiscal 2018. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606)*, deferring the effective date of ASU 2014-09 by one year. The Company can elect to adopt the provisions of ASU 2014-09 for annual periods beginning after December 31, 2017, including interim periods within that reporting period. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on the consolidated financial statements and has not yet determined the method by which the Company will adopt the standard.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

3. Summary of Significant Accounting Policies (continued)

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU provides guidance on management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures in the notes to the financial statements. The amendments in this ASU should help reduce the diversity in the timing and content of disclosures in the notes to the financial statements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of the pending adoption of ASU 2014-15 on the consolidated financial statements and has not yet determined the timing at which the Company will adopt the standard.

In April 2015, the FASB issued ASU 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. This ASU provides guidance that simplifies the presentation of debt issuance costs by amending the accounting guidance to require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability. The amendments are consistent with the accounting guidance related to debt discounts. This guidance is effective for the first interim or annual period beginning after December 15, 2015. The Company adopted this guidance in the first quarter of fiscal 2016.

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

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

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

In March 2016, the FASB issued guidance to simplify several aspects of the accounting for share-based payments transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for annual and interim periods beginning after December 31, 2016. Early adoption is permitted for an entity in an interim or annual period. We are currently evaluating the effect that the updated standard will have on our financial statements, but expect the guidance will add modest volatility in our equity-based compensation expense, provision for income taxes, and net income (loss).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

4. Intangible assets

Intangible assets consist of the following:

	June 30, 2016	December 31, 2015
Patents, at cost	$3,502,135	$3,502,135
Less accumulated amortization	(3,348,757)	(3,195,379)
Net intangible assets	$153,378	$306,756

The aggregate amortization charged to operations was $76,689 for the three months ended June 30, 2016 and 2015 and $153,378 for the six months ended June 30, 2016 and 2015.

5. Accrued expenses

Accrued expenses consist of the following:

	June 30, 2016	December 31, 2015
Accrued former executive payment	$100,000	$100,000
Accrued audit and tax preparation	46,752	93,500
Accrued directors and advisors fees	45,333	-
Accrued outside services	43,105	58,813
Accrued legal professional fees	30,500	76,500
Accrued clinical study expenses	13,650	22,777

Accrued other	16,483	7,784
	$295,823	$359,374

6. Notes payable, related parties

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

On June 15, 2015, the Company and HealthTronics, Inc. entered into an amendment (the "Note Amendment") to amend certain provisions of the notes payable, related parties. The Note Amendment provides for the extension of the due date to January 31, 2017. In the period ending March, 31, 2016, the Company reclassified the outstanding principal balance from non-current liabilities to current liabilities. In connection with the Note Amendment, the Company entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. The notes payable, related parties will bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company's patents or other intellectual property rights.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

6. 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.

The notes payable, related parties had an aggregate outstanding principal balance of $5,334,234, net of $38,509 debt discount at June 30, 2016 and $5,348,112, net of $24,631 debt discount at December 31, 2015, respectively.

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

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.

Accrued interest currently payable totaled $108,224 and $239,803 at June 30, 2016 and December 31, 2015, respectively. Interest expense on notes payable, related parties totaled $108,224 and $80,968 for the three months ended June 30, 2016 and 2015, respectively, and $260,937 and $161,039 for the six months ended June 30, 2016 and 2015, respectively.

7. Promissory notes payable

On February 1, 2016, the Company entered into a financing transaction for the sale of an 8% Convertible Promissory Note (the “$58,300 Convertible Note”) and warrants (the “Class M Warrants”) in the principal amount of $58,300 each, with gross proceeds of $50,000 to the Company after payment of a 10% original issue discount and related professional expenses. 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 $58,300 Convertible Note was offered and sold to two accredited investors, with gross proceeds of $106,000 to the Company.

The $58,300 Convertible Note and Class M Warrants were issued pursuant to the terms of a purchase agreement among the Company and the Investors. The convertible note is an unsecured obligation of the Company and, unless earlier redeemed, matures on August 1, 2016. The Company has the right to prepay the convertible note and accrued interest during the first sixty (60) days following the date of issuance. During that time, the amount of any prepayment during the first sixty (60) days is 120% of the outstanding amounts owed, and the amount of the prepayment increases every subsequent thirty (30) days. Each Class M Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on February 21, 2021.

The $58,300 Convertible Note is convertible, at any time from the issuance date, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 30% of the lowest reported sale price of the Company’s common stock for the 20 trading days immediately prior to (i) the date of the purchase agreement or (ii) the voluntary conversion date.

The $58,300 Convertible Note contained put options that may require the Company to repay the debt before its maturity. The $58,300 Convertible Note holder has rights to demand repayment in the event of defaults. However, since the put is contingent on an event of default, and no principal is due until maturity, the likelihood of the other default provision is considered to be very remote especially given the term of the $58,300 Convertible Note is six months.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

7. Promissory notes payable (continued)

The promissory notes payable had an aggregate outstanding principal balance of $115,933, net of $4,473 debt issuance costs at June 30, 2016.

8. Income taxes

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

At June 30, 2016, the Company had federal net operating loss ("NOL") carryforwards of $70,096,802 for tax years through the year ended December 31, 2015, that will begin to expire in 2025. The use of deferred tax assets, including federal net operating losses, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, *Income Taxes*, the Company's management believes that there is not sufficient evidence at June 30, 2016 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2016. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including NOL carryforwards.

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

9. Equity transactions

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 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.

At the closing of the 2016 Equity Offering, the Company paid Newport Coast Securities, Inc., the placement agent for the equity offering, cash compensation based on the gross proceeds of the private placement and 3,001,667 Class L Warrants.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

9. Equity transaction (continued)

Series A Warrant Conversion

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

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

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

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

10. Preferred Stock

The Company’s Articles of Incorporation authorize the issuance of up to 5,000,000 shares of “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by the board of directors. On January 12, 2016, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series B Convertible Preferred Stock of the Company (the “Certificate of Designation”) with the Nevada Secretary of State. The Certificate of Designation amends the Company’s Articles of Incorporation to designate 293 shares of preferred stock, par value $0.001 per share, as Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock has a stated value of $1,000 per share. On January 13, 2016, in connection with the Series A Warrant Conversion, the Company issued 293 shares of Series B Convertible Preferred Stock (for a more detailed discussion regarding the Series A Warrant Conversion, see Note 9).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

10. Preferred Stock (continued)

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

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

On March 14, 2014, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series A Convertible Preferred Stock of the Company (the "Certificate of Designation") with the Nevada Secretary of State. The Certificate of Designation amends the Company's Articles of Incorporation to designate 6,175 shares of preferred stock, par value $0.001 per share, as Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock has a stated value of $1,000 per share. On March 17, 2014, in connection with a Private Placement, the Company issued 6,175 shares of Series A Convertible Preferred Stock. As of January 6, 2015 there were no outstanding shares of Series A Convertible Preferred Stock.

11. Warrants

A summary of the warrant activity as of June 30, 2016 and December 31, 2015, and the changes during the six months ended June 30, 2016, is presented as follows:

Warrant class	Outstanding as of December 31, 2015	Issued	Exercised	Converted	Expired	Outstanding as of June 30, 2016
Class E Warrants	3,576,737	-	-	-	(3,576,737)	-
Class F Warrants	300,000	-	-	-	-	300,000
Class G Warrants	1,503,409	-	-	-	-	1,503,409
Class H Warrants	1,988,095	-	-	-	-	1,988,095
Class I Warrants	1,043,646	-	-	-	-	1,043,646
Class J Warrants	629,378	4,012,289	-	-	-	4,641,667
Class K Warrants	3,310,000	1,890,000	-	-	-	5,200,000
Class L Warrants	-	33,018,337	-	-	-	33,018,337
Class M Warrants	-	1,943,333	-	-	-	1,943,333
Series A Warrants	25,951,421	-	-	(23,701,427)	-	2,249,994
	38,302,686	40,863,959	-	(23,701,427)	(3,576,737)	51,888,481

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

11. Warrants (continued)

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

	Exercise price/share	Expiration date
Class E Warrants	$ 4.00	April 2016
Class F Warrants	$ 0.35	February 2018
Class G Warrants	$ 0.80	July 2018
Class H Warrants	$ 0.80	July 2018
Class I Warrants	$ 0.85	September 2018
Class J Warrants	$ 0.06	February 2019
Class K Warrants	$ 0.08	June 2025
Class L Warrants	$ 0.08	March 2019
Class M Warrants	$ 0.06	February 2021
Series A Warrants	$ 0.06	March 2019

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

The exercise price of the Class J Warrants, Class K Warrants, Class M 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, Class J and Class M Warrants was adjusted to $0.06 due to the 2016 Equity Offering (see Note 9). The Class J Warrants and Class K Warrants may be exercised on a physical settlement or on a cashless basis. The Series A Warrants may be exercised on a physical settlement basis if a registration statement underlying the warrants is effective. If a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale by the holder of the Series A Warrants, then the holder may exercise the warrants on a cashless basis.

The Class J Warrants, the Class K Warrants, the Class M Warrants, the Series A Warrants and the Series B Warrants are derivative financial instruments. The estimated fair value of the Class J Warrants at the date of grant was $12,776. The related debt discount was accreted to interest expense through the maturity date of the related note. The estimated fair value of the Class K Warrants at the date of grant was $36,989 and recorded as debt discount, which will be accreted to interest expense through the maturity date of the related notes payable, related parties. The estimated fair value of the Class M Warrants at the date of grant was $9,091 and the estimated value of the conversion option of the note at the date of grant was $66,331. The related debt discount was accreted to interest expense through the maturity date of the related note. 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

11. Warrants (continued)

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.

A summary of the changes in the warrant liability as of June 30, 2016 and December 31, 2015, and the changes during the three and six months ended June 30, 2016, is presented as follows:

	Class J Warrants	Class K Warrants	Class M Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2015	$ 2,900	$ 22,700	$ -	$ 112,500	$ 138,100
Issued	-	-	75,422	-	75,422
Change in fair value	17,600	(6,600)	878	(102,600)	(90,722)
Warrant liability as of March 31, 2016	$ 20,500	$ 16,100	$ 76,300	$ 9,900	$ 122,800
Issued	-	25,350	-	-	25,350
Change in fair value	(6,600)	(16,150)	(2,400)	(3,100)	(28,250)
Warrant liability as of June 30, 2016	$ 13,900	$ 25,300	$ 73,900	$ 6,800	$ 119,900

12. Commitments and contingencies

Operating Leases

Rent expense for the three months ended June 30, 2016 and 2015, was $40,455 and $38,505, respectively and for the six months ended June 30, 2016 and 2015, was $82,974 and $71,912, respectively.

Litigation

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

13. Stock-based compensation

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Stock Incentive Plan"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to four years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At June 30, 2016 and December 31, 2015, the Stock Incentive Plan reserved 12,500,000 shares of common stock for grant.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

13. Stock-based compensation (continued)

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 six months ended June 30, 2016 and 2015:

	2016	2015
Weighted average expected life in years	5.0	5.5
Weighted average risk free interest rate	1.10 %	2.41 %
Weighted average volatility	140.0%	136.1%
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, $112,050 and $22,235 for the three months ended June 30, 2016 and 2015, respectively and $116,550 and $50,062 for the six months ended June 30, 2016 and 2015, respectively.

A summary of option activity as of June 30, 2016 and December 31, 2015, and the changes during the three and six months ended June 30, 2016, is presented as follows:

	Options	Weighted

		Average Exercise Price per share
Outstanding as of December 31, 2015	10,073,385	$ 0.62
Granted	-	$ -
Exercised	-	$ -
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of March 31, 2016	10,073,385	$ 0.55
Granted	3,300,000	$ 0.04
Exercised	-	$ -
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of June 30, 2016	13,373,385	$ -
Exercisable	13,273,385	$ 0.43

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at June 30, 2016 and December 31, 2015. The aggregate intrinsic value for all vested and exercisable options was $0 at June 30, 2016 and December 31, 2015.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

13. Stock-based compensation (continued)

The weighted average remaining contractual term for outstanding exercisable stock options was 7.63 and 7.46 years as of June 30, 2016 and December 31, 2015, respectively.

A summary of the Company's nonvested options as of June 30, 2016 and December 31, 2015, and changes during the three and six months ended June 30, 2016, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding as of December 31, 2015	175,002	$ 0.36
Granted	-	$ -
Vested	-	$ -
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of March 31, 2016	175,002	$ 0.36
Granted	3,300,000	$ 0.04
Vested	(3,375,002)	$ 0.05
Cancelled	-	$ -
Forfeited or expired	-	$ -
Outstanding as of June 30, 2016	100,000	$ 0.21

14. Earnings (loss) per share

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

As a result of the net loss for the six months ended June 30, 2016 and 2015, 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 65,261,866 shares and 45,609,516 shares at June 30, 2016 and 2015, respectively.

15. Subsequent events

Convertible Debentures

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 up to $500,000, with gross proceeds of $450,000 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

15. Subsequent events (continued)

The Debenture was issued pursuant to the terms of a purchase agreement among the Company and the Investor. 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 shall pay to Investor a non-accountable fee (the “Commitment Fee”) of (i) Two Thousand Five Hundred and 00/100 Dollars ($2,500.00) and (ii) Eight Hundred Thirty Five Thousand (835,000) shares of Restricted Stock for Investor’s expenses and analysis performed in connection with the analysis of the Company and the propriety of the Investor’s making the contemplated investment. The Commitment Fee shall be paid on the signing closing date immediately upon receipt of the signing purchase price if Investory does not withhold such amounts from the signing purchase price.

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 to convert the Conversion Amount (as defined below) into Conversion Shares, at a conversion price for each share of Common Stock (the “Conversion Price”) equal to either (i) if the Company is 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 shall issue irrevocable instructions to its Transfer Agent regarding conversions such that the transfer agent shall be authorized and instructed to issue Conversion Shares upon its receipt of a Notice of Conversion without further approval or authorization from the Company. For purposes of this Debenture, the “Conversion Amount” shall mean the sum of (A) all or any portion of the outstanding Principal Amount of this Debenture, as designated by the Holder upon exercise of its right of conversion plus (B) any interest, pursuant to Section 10 or otherwise, that has accrued on the portion of the Principal Amount that has been designated for payment pursuant to (A).

The Debenture may be called for redemption by the Company, upon not more than two (2) days written notice, for an amount (the “Redemption Price”) equal to: (i) if the Redemption Date (as defined below) is ninety (90) days or less from the date of issuance of this Debenture, One Hundred Five percent (105%) of the sum of the Principal Amount so redeemed plus accrued interest, if any; (ii) if the Redemption Date is greater than or equal to ninety one (91) days from the date of issuance of this Debenture and less than or equal to one hundred twenty (120) days from the date of issuance of this Debenture, One Hundred Fifteen percent (115%) of the sum of the Principal Amount so redeemed plus accrued interest, if any; (iii) if the Redemption Date is greater than or equal to one hundred twenty one (121) days from the date of issuance of this Debenture and less than or equal to one hundred fifty (150) days from the date of issuance of this Debenture, One Hundred Twenty percent (120%) of the sum of the Principal Amount so redeemed plus accrued interest, if any; (iv) if the Redemption Date is greater than or equal to one hundred fifty one (151) days from the date of issuance of this Debenture and less than or equal to one hundred eighty (180) days from the date of issuance of this Debenture, One Hundred Thirty percent (130%) of the sum of the Principal Amount so redeemed plus accrued interest, if any; and (v) if either (1) the Debentures are in default but the Holder consents to the redemption notwithstanding such default or (2) the Redemption Date is greater than or equal to one hundred eighty one (181) days from the date of issuance of this Debenture, one hundred forty percent (140%) of the sum of the Principal Amount so redeemed plus accrued interest, if any. The date upon which the Debentures are redeemed and paid shall be referred to as the “Redemption Date” (and, in the case of multiple redemptions of less than the entire outstanding Principal Amount, each such date shall be a Redemption Date with respect to the corresponding redemption).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

15. Subsequent events (continued)

On July 29, 2016, the Company received gross proceeds of $175,000 from the Convertible Debenture, which is the first tranche of principal amount of $200,000, net of the $20,000 original debt discount, the $2,500 Commitment Fee and $2,500 in legal fees.

$58,300 Convertible Note Repayment

In August 2016, the Company repaid the $58,300 Convertible Note to both accredited investors in full, with accrued interest and a prepayment penalty of 140% of the total outstanding balance.

2016 Private Placement

On August 11, 2016, opened a private placement of securities (the “2016 Private Placement”) with select accredited investors. The 2016 Private Placement is offering Units (the “Units”) at a purchase price of $0.06 per Unit, with each Unit consisting of (i) one (1) share of our common stock, $0.001 par value (the “Common Stock”) and, (ii) one (1) detachable warrant (the “Warrants”) to purchase one (1) share of our Common Stock at an exercise price of $0.08 per share.

The Company and the accredited investors are executing and delivering this 2016 Private Placement 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”), and Rule 506 of Regulation D (“Regulation D”) as promulgated by the United States Securities and Exchange Commission (the “Commission”) under the Securities Act

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.

The Company has collected $130,000 to date from accredited investors.

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, 2015 included in our Annual Report on Form 10-K, filed with the SEC on March 30, 2015.

Overview

We are an acoustic pressure shock wave technology company using a patented system of noninvasive, high-energy, acoustic pressure shock waves for indications such as regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of skin, musculoskeletal tissue 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. A *de novo* petition was sent to FDA on July 23, 2016 requesting Agency review and classification of the dermaPACE device for treating diabetic foot ulcers as a Class II device, for possible approval in late 2016 or early 2017.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic, plastic/cosmetic and cardiac/endovascular 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 musculoskeletal chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe, Asia and Asia/Pacific. Our lead product candidate for the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

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

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

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, for sterilizing food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

Recent Developments

The U.S. Food and Drug Administration (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 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 primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

A total of 336 patients entered the dermaPACE study at 37 sites. The patients in the study were followed for a total of 24 weeks. The study's primary endpoint, wound closure, was defined as "successful" if the skin was 100% reepithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits.

A summary of the key study findings were as follows:

Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks, 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 filed with the FDA the clinical module of the dermaPACE PMA application in June 2011. In December 2011, we received a major deficiency letter from the FDA regarding the FDA's review of the dermaPACE PMA. The FDA issues a major deficiency letter to the applicant when the PMA lacks significant information necessary for the FDA to complete its review or to determine whether there is reasonable assurance that the device is safe and effective for its intended use. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

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

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

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan for the supplemental clinical trial incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the initial clinical trial (discussed above). Similar to the initial trial, four dermaPACE procedures are administered during the first two weeks following subject enrollment. In the supplemental clinical trial, however, up to four additional dermaPACE procedures are delivered bi-weekly, between weeks 4 and 10 following subject enrollment, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

The patient enrollment began in June 2013 for the supplemental clinical trial and by April 2014, we had enrolled the minimum number of 90 patients in the clinical trial, which represented the number of patients for the first interim analysis by the independent Data Monitoring Committee (DMC). In September 2014, we reported that the DMC had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the supplemental clinical trial and recommended we continue enrollment of patients into the study up to the next predefined patient analysis point of 130 patients. We completed enrollment for the 130 patients in November 2014 and suspended further enrollment at that time.

In May 2015, the DMC performed an analysis on the 130 patients of the primary efficacy endpoint of the rate of 100% complete wound closure at the 12-week endpoint for the dermaPACE treated patients as compared to the sham-control patients and the safety data. The DMC completed its review and noted there were no safety issues. The DMC reported the Monitoring Success Criterion for primary efficacy endpoint of 100% complete wound closure at 12 weeks had not been met and, assuming similar trends for any additional patents enrolled, will likely not be met at the next predefined analysis point of 170 patients. The Monitoring Success Criterion is a predictive probability of dermaPACE achieving statistical significance in the rate of 100% complete wound closure at 12 weeks as compared to the rate for sham-control. As per its charter, the DMC's review was limited to only the 12-week endpoint data. We decided to stop any further enrollment in the supplemental clinical trial after this review.

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

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

In October 2015 after freezing and locking the data, we began to perform 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 the 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 appropriately be considered for classification into Class II as there is no legally marketed predicate device and that there is not an existing Class III classification regulation or one or more approved PMA's (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*, in which case the dermaPACE will be classified as Class II and may be marketed immediately.

Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At June 30, 2016, we had cash and cash equivalents totaling $122,948. Management expects the cash used in operations for the Company during the next two quarters of 2016 will be approximately $175,000 to $225,000 per month as resources are devoted to an office relocation and upgrade of our information technology platform review, preparation of any additional analysis of the clinical data results as requested by the FDA and preparation of the launch of the dermaPACE upon FDA approval.

The continuation of our business is dependent upon raising additional capital during the second and third quarters of 2016 to fund operations. Management's plans are to obtain additional capital in 2016 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 June 30, 2015, we had an accumulated deficit of $95,841,107. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next few years as we prepare our FDA submission for the dermaPACE device for the treatment of diabetic foot ulcers but if we obtain FDA approval and are able to successfully commercialize, market and distribute the dermaPACE device, then we hope to partially or completely offset these losses within the next few years. We incurred a net loss of $2,846,699 and $2,680,648 during the six months ended June 30, 2016 and 2015, respectively. These operating losses create an uncertainty about our ability to continue as a going concern. 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, 2015, filed with the SEC on March 30, 2016.

Critical Accounting Policies and Estimates

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

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

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements filed with our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 30, 2016, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, intangible assets, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

Research and Development Costs

We expense costs associated with research and development activities as incurred. We evaluate payments made to suppliers, 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 market, which is valued using the first in, first out (FIFO) method, and consists primarily of devices and the component material for assembly of finished products, less reserves for obsolescence.

Intangible Assets

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

Stock-based Compensation

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

In accordance with ASC 718, *Compensation – Stock Compensation*, the fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The expected terms of options granted represent the period of time that options granted are estimated to be outstanding and are derived from the contractual terms of the options granted. We amortize the fair value of each option over each option’s vesting period.

Income Taxes

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes*. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets, including loss carryforwards, when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

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

Results of Operations for the Three Months ended June 30, 2016 and 2015 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended June 30, 2016 were $203,406, compared to $239,983 for the same period in 2015, a decrease of $36,577, or 15%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The decrease in revenues for 2016 was due to higher sales of new orthoPACE devices and applicators in Europe and Asia/Pacific in 2015, there were four new devices sold in 2015 and two new devices and two demonstration devices sold in 2016.

Cost of revenues for the three months ended June 30, 2016 were $77,988, compared to $75,779 for the same period in 2015. Gross profit as a percentage of revenues was 62% for the three months ended June 30, 2016, compared to 68% for the same period in 2015. The decrease in gross profit as a percentage of revenues in 2016 was due to sale of demonstration devices at a lower rate and lower number of new applicators sold in 2016 as compared to 2015.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2016 were $476,167, compared to $456,789 for the same period in 2015, an increase of $19,378, or 4%. 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 increased in 2016 as a result of stock based compensation for options issued in July 2016 and higher bonus expense. This is partially offset by lower payments to third party clinical sites participating in the dermaPACE clinical study as the patient enrollment was completed in 2015 and lower consulting related costs as the data results were also completed in 2015, and higher consulting expenses related to the pre-submission package to the FDA in 2016.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2016 were $589,896, as compared to $636,570 for the same period in 2015, a decrease of $46,674, or 7%. The decrease in general and administrative expenses is primarily due to reduced salary and related costs as a result of reduction in headcount in July 2015 and lower legal fees and is partially offset by stock based compensation for options issued in July 2016.

Other Income (Expense)

Other income (expense) was a net expense of $103,952 for the three months ended June 30, 2016, as compared to a net expense of $514,764 for the same period in 2015, a decrease in other expense of $410,812. The decrease in other expense for 2016 was due to gain on warrant valuation related to the conversion of the majority of the Series A Warrants into common and preferred shares of stock and lower stock price. In addition, there was higher interest expense in 2016 related to the amended terms of the notes payable, related parties and the issuance of promissory notes.

Provision for Income Taxes

At June 30, 2016, we had federal net operating loss carryforwards of $70,096,802 through the year ended December 31, 2015 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 June 30, 2016 was $1,122,123, or ($0.01) per basic and diluted share, compared to a net loss of $1,521,533, or ($0.02) per basic and diluted share, for the same period in 2015, a decrease in the net loss of $399,410, or 26%. The decrease in the net loss for 2016 was primarily due to the gain on the warrant valuation.

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

Results of Operations for the Six Months ended June 30, 2016 and 2015 (Unaudited)

Revenues and Cost of Revenues

Revenues for the six months ended June 30, 2016 were $472,730, compared to $450,435 for the same period in 2015, an increase of $22,295, or 5%. Revenues resulted primarily from sales in Europe, Asia and Asia/Pacific of our orthoPACE device and related applicators. The increase in revenues for 2016 was due to higher sales of orthoPACE devices and refurbishment of applicators as well as higher sales of wound kits as compared to 2015.

Cost of revenues for the six months ended June 30, 2016 were $151,169, compared to $134,597 for the same period in 2015. Gross profit as a percentage of revenues was 68% for the three months ended June 30, 2016, compared to 70% for the same period in 2015. The decrease in gross profit as a percentage of revenues in 2016 was due to sale of demonstration devices at a lower rate and lower number of new applicators sold in 2016 as compared to 2015 which is partially offset by higher gross profit margin sale of wound kits.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2016 were $786,122, compared to $1,091,412 for the same period in 2015, a decrease of $305,290, or 28%. 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 2016 as a result of lower payments to third party clinical sites participating in the dermaPACE clinical study as the patient enrollment was completed in 2015 and lower consulting related costs as the data results were also completed in 2015, and higher consulting expenses related to the pre-submission package to the FDA in 2016. This is partially offset by stock based compensation for options issued in July 2016 and higher bonus expense.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2016 were $1,089,028, as compared to $1,202,862 for the same period in 2015, a decrease of $113,834, or 9%. The decrease in general and administrative expenses is primarily due to reduced salary and related costs as a result of reduction in headcount in July 2015 and lower legal fees and is partially offset by stock based compensation for options issued in July 2016.

Other Income (Expense)

Other income (expense) was a net expense of $1,138,059 for the six months ended June 30, 2016, as compared to a net expense of $546,984 for the same period in 2015, an increase in other expense of $591,075. The increase in other expense for 2016 was due to loss on warrant valuation related to the conversion of the majority of the Series A Warrants into common and preferred shares of stock which is partially offset by a lower stock price for the calculation of the valuations at June 30, 2016. In addition, there was higher interest expense in 2016 related to the amended terms of the notes payable, related parties and the issuance of promissory notes.

Provision for Income Taxes

At June 30, 2016, we had federal net operating loss carryforwards of $70,096,802 through the year ended December 31, 2015 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 six months ended June 30, 2016 was $2,846,699, or ($0.03) per basic and diluted share, compared to a net loss of $2,680,648, or ($0.04) per basic and diluted share, for the same period in 2015, an increase in the net loss of $166,051, or 6%. The increase in the net loss for 2016 was primarily due to the loss on the Series A warrant conversion which is partially offset by lower operating expenses as noted above.

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

Liquidity and Capital Resources

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At June 30, 2016, we had cash and cash equivalents totaling $122,948. Management expects the cash used in operations for the Company during the next two quarters of 2016 will be approximately $175,000 to $225,000 per month as resources are devoted to an office relocation and upgrade of our information technology platform review, preparation of any additional analysis of the clinical data results as requested by the FDA and preparation of the launch of the dermaPACE upon FDA approval.

The continuation of our business is dependent upon raising additional capital during the third quarter of 2016 to fund operations. Management has entered into a Convertible Debenture agreement and initiated a 2016 Private Placement Offering (see Note 15) to obtain capital. Management's plans are to obtain additional capital in 2016 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

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

Cash and cash equivalents decreased by $29,982 for the six months ended June 30, 2016 and decreased by $1,931,344 for the six months ended June 30, 2015. For the six months ended June 30, 2016 and 2015, net cash used by operating activities was $1,731,124 and $1,917,858, 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 six months ended June 30, 2016, as compared to the same period for 2015, of $186,734, or 110%, was primarily due to the decreased operating expenses in 2016, as compared to 2015, and the non-cash loss on exchange of warrants in 2016. Net cash provided by financing activities for the six months ended June 30, 2016 was $1,702,855, which consisted of the net proceeds from the 2016 Equity Offering of $1,596,855 and the proceeds from convertible promissory notes of $106,000.

Segment and Geographic Information

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

Contractual Obligations

Our major outstanding contractual obligations relate to our operating lease for our facility, purchase and supplier obligations for product component materials and equipment, and our notes payable. We have disclosed these obligations in our most recent Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 30, 2016.

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 June 30, 2016. Based on this evaluation, the Acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2016.

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

Changes in Internal Control over Financial Reporting

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

PART II — OTHER INFORMATION

Item 6. EXHIBITS

Exhibit No.	Description
4.1*	Amendment to Class K Warrant Agreement.
10.1*	Second amendment to promissory notes entered into as of June 28, 2016 by and among SANUWAVE Health, Inc., SANUWAVE, Inc. and HealthTronics, Inc.
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.

† 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: August 15, 2016	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)	August 15, 2016
By: /s/ *Lisa E. Sundstrom* Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	August 15, 2016
By: /s/ *John F. Nemelka* Name: John F. Nemelka	Director	August 15, 2016
By: /s/ *Alan L. Rubino*	Director	August 15, 2016

Name: Alan L. Rubino

By: /s/ A. Michael Stolarski Director August 15, 2016

Name: A. Michael Stolarski

EXHIBIT INDEX

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