SANUWAVE Health, Inc.
Form 10-Q
May 15, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2018

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 (State or other jurisdiction of incorporation or organization)	20-1176000 (I.R.S. Employer Identification No.)
3360 Martin Farm Road, Suite 100 Suwanee, GA (Address of principal executive offices)	30024 (Zip Code)

(770) 419-7525
(Registrant's telephone number, including area code)

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

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

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

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

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

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

As of May 11, 2018, there were issued and outstanding 151,378,374 shares of the registrant's common stock, $0.001 par value.

SANUWAVE Health, Inc.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of SANUWAVE Health, Inc. and its subsidiaries (“SANUWAVE” or the “Company”) contains forward-looking statements. All statements in this Quarterly Report on Form 10-Q, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company’s future financial results, the Company’s near term cash requirements and cash sources, clinical trial results, regulatory approvals, operating results, business strategies, projected costs, products, competitive positions, management’s plans and objectives for future operations, and industry trends. These forward-looking statements are based on management’s estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan “anticipate,” “believe,” “estimate,” “predict,” “potential” and “continue,” the negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission (the “SEC”), specifically the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018 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, 2017, filed on March 29, 2018.

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

PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS (UNAUDITED)

SANUWAVE
HEALTH, INC.
AND
SUBSIDIARIES

CONDENSED
CONSOLIDATED
BALANCE
SHEETS
(UNAUDITED)

	March 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$154,205	$730,184
Accounts receivable, net of allowance for doubtful accounts of $73,184 in 2018 and $92,797 in 2017	151,684	152,520
Contract assets (Note 6)	55,700	-
Inventory, net	264,266	231,532
Prepaid expenses	200,960	90,288
TOTAL CURRENT ASSETS	826,815	1,204,524
PROPERTY AND EQUIPMENT, net (Note 4)	63,073	60,369
OTHER ASSETS	17,253	13,917
TOTAL ASSETS	$907,141	$1,278,810
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$822,760	$1,496,523
Accrued expenses (Note 5)	608,856	673,600
Accrued employee compensation	70,502	1,680
Contract liabilities (Note 6)	35,840	-
Advances from related and unrelated parties (Note 7)	12,000	310,000
Line of credit, related parties (Note 8)	375,729	370,179

Convertible promissory notes, net (Note 9)	2,004,541	455,606
Note payable, product, related party (Note 10)	94,058	-
Interest payable, related parties (Note 11)	685,907	685,907
Warrant liability (Note 15)	4,798,727	1,943,883
Notes payable, related parties, net (Note 11)	5,260,243	5,222,259
TOTAL CURRENT LIABILITIES	14,769,163	11,159,637
NON-CURRENT LIABILITIES		
Contract liabilities	73,374	-
TOTAL NON-CURRENT LIABILITIES	73,374	-
TOTAL LIABILITIES	14,842,537	11,159,637
COMMITMENTS AND CONTINGENCIES (Note 16)		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 authorized; 6,175 shares issued and 0 shares outstanding in 2017 and 2016 (Note 14)	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 authorized; 293 shares issued and 0 shares outstanding in 2017 and 2016, respectively (Note 14)	-	-
PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,532 shares authorized; no shares issued and outstanding (Note 14)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 141,050,550 and 139,300,122 issued and outstanding in 2018 and 2017, respectively (Note 13)	141,051	139,300
ADDITIONAL PAID-IN CAPITAL	96,794,440	94,995,040
ACCUMULATED DEFICIT	(110,828,039)	(104,971,384)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(42,848)	(43,783)
TOTAL STOCKHOLDERS' DEFICIT	(13,935,396)	(9,880,827)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$907,141	$1,278,810

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
REVENUES	$344,272	$149,569
COST OF REVENUES (exclusive of depreciation shown below)	165,466	55,144
OPERATING EXPENSES		
Research and development	349,444	260,338
General and administrative	945,606	448,606
Depreciation	5,016	6,120
TOTAL OPERATING EXPENSES	1,300,066	715,064
OPERATING LOSS	(1,121,260)	(620,639)
OTHER INCOME (EXPENSE)		
(Loss) gain on warrant valuation adjustment	(2,973,682)	323,223
Interest expense, net	(1,744,967)	(192,738)
Loss on foreign currency exchange	(16,746)	(3,378)
TOTAL OTHER INCOME (EXPENSE), NET	(4,735,395)	127,107
NET LOSS	(5,856,655)	(493,532)
OTHER COMPREHENSIVE INCOME		
Foreign currency translation adjustments	935	1,785
TOTAL COMPREHENSIVE LOSS	$(5,855,720)	$(491,747)

LOSS PER SHARE:		
Net loss - basic and diluted	$(0.04)	$-
Weighted average shares outstanding - basic and diluted	139,754,044	138,042,070

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(5,856,655)	$(493,532)
Adjustments to reconcile loss from continuing operations to net cash used by operating activities		
Depreciation	5,016	6,120
Change in allowance for doubtful accounts	(19,613)	5,152
Loss (gain) on warrant valuation adjustment	2,973,682	(323,223)
Amortization of debt issuance costs	1,473,872	-
Amortization of debt discount	37,984	55,900
Stock issued for consulting services	79,000	-
Changes in assets - (increase)/decrease		
Accounts receivable - trade	20,449	4,278
Inventory	(32,734)	29,074
Prepaid expenses	(110,672)	(27,554)
Contract assets	(55,700)	
Other	(3,336)	(55)
Changes in liabilities - increase/(decrease)		
Accounts payable	(553,763)	320,377
Accrued expenses	(64,744)	171,741
Accrued employee compensation	68,822	-
Contract liabilties	109,214	-
Accrued interest	80,613	-

Interest payable, related parties	-	136,838
NET CASH USED BY OPERATING ACTIVITIES	(1,848,565)	(114,884)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(7,720)	-
NET CASH USED BY INVESTING ACTIVITIES	(7,720)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from convertible promissory notes, net	1,159,785	-
Proceeds from note payable, product	96,708	-
Proceeds from warrant exercise	13,528	77,066
Advances from related parties	12,000	-
Payments on note payable, product	(2,650)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,279,371	77,066
EFFECT OF EXCHANGE RATES ON CASH	935	1,785
NET DECREASE IN CASH AND CASH EQUIVALENTS	(575,979)	(36,033)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	730,184	133,571
CASH AND CASH EQUIVALENTS, END OF PERIOD	$154,205	$97,538
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$151,227	$-
Cash paid for note payable, product	$2,650	$-
NONCASH INVESTING AND FINANCING ACTIVITIES		
Stock issued for services	$79,000	$-
Cashless exercise of warrants	$118,838	$56,740
Advances from related and unrelated parties converted to Convertible promissory notes	$310,000	$-
Accounts payable converted to Convertible promissory notes	$120,000	$-
Beneficial conversion feature on 10% convertible promissory notes	709,827	-
Beneficial conversion feature on convertible promissory note	35,396	-
Beneficial conversion feature on convertible debt	$745,223	$-
Warrants issued with 10% convertible promissory notes	$808,458	$-
Warrants issued with convertible promissory note	36,104	-
Warrants issued for debt	$844,562	$-

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2018

1. Nature of the Business

SANUWAVE Health, Inc. and subsidiaries (the "Company") is a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. The Company's initial focus is regenerative medicine – utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. 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. On December 28, 2017, the U.S. Food and Drug Administration (the "FDA") notified the Company to permit the marketing of the dermaPACE System for the treatment of diabetic foot ulcers in the United States.

The Company's portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. In 2018, the Company has started marketing the dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

2. Going Concern

The Company does not currently generate significant recurring revenue and will require additional capital during the second and third quarters of 2018. As of March 31, 2018, the Company had an accumulated deficit of $110,828,039 and cash and cash equivalents of $154,205. For the three months ended March 31, 2018 and 2017, the net cash used by operating activities was $1,848,565 and $114,884, respectively. The Company incurred a net loss of $5,856,655 for the three months ended March 31, 2018 and a net loss of $5,537,936 for the year ended December 31, 2017. The operating losses and the Events of Default on the Note payable, product, related party (see Note 10) and Notes payable, related parties (see Note 11) create an uncertainty about the Company's ability to continue as a going concern.

The continuation of the Company's business is dependent upon raising additional capital during the second and third quarters of 2018 to fund operations. Management's plans are to obtain additional capital in 2018 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

3.
Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and footnotes required by United States generally accepted accounting principles for complete financial statements. The financial information as of March 31, 2018 and for the three months ended March 31, 2018 and 2017 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2018.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2018

3.
Summary of Significant Accounting Policies (continued)

The condensed consolidated balance sheet at December 31, 2017 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, 2017, filed with the SEC on March 29, 2018.

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 was declared effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective method, which requires the standard to be applied to each prior period presented, or (ii) a modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to the opening retained earnings in the period of adoption. In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2018 instead of the previous effective date, which was the first quarter of fiscal 2017. This one year deferral was issued by the FASB in ASU 2015-14, Revenue from Contracts with Customers (Topic 606). The Company adopted the new standard on a modified retrospective basis as of January 1, 2018. The Company completed an assessment of customer contracts and concluded that the adoption of this ASU did not have a material impact on our condensed, consolidated financial statements; therefore, no cumulative catch-up adjustment was recorded to prior periods. The disclosures related to revenue recognition have been significantly expanded under the standard, specifically around the quantitative and qualitative information about performance obligations and disaggregation of revenue. The expanded disclosure requirements are included in this Form 10-Q (see Notes 6 and 17).

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

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2018

3.
Summary of Significant Accounting Policies (continued)

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments (Topic 230). This ASU will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The ASU will be effective for fiscal years beginning after December 15, 2017. This standard will require adoption on a retrospective basis unless it is impracticable to apply, in which case it would be required to apply the amendments prospectively as of the earliest date practicable. The new standard was adopted during the first quarter of 2018 using a retrospective transition method. The adoption of this guidance did not have a material impact on our financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480): Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this ASU addresses the complexity and reporting burden associated with the accounting for freestanding and embedded instruments with down round features as liabilities subject to fair value measurement. Part II of this ASU addresses the difficulty of navigating Topic 480. Part I of this ASU will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for an entity in an interim or annual period. Management is evaluating the requirements of this guidance and has not yet determined the impact of the pending adoption on the Company’s financial position or results of operations.

In February 2018, the FASB issued ASU 2018-02, Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This ASU requires reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act (the"TCJA"). The amount of the reclassification is the difference between the historical 35% corporate income tax rate and the newly enacted 21% corporate income tax rate. Because the amendments only relate to the reclassification of the income tax effects of the Tax Cuts and Jobs Act, the underlying guidance that requires that the effect of a change in tax laws of rates be included in income from continuing operations is not affected. This ASU is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. In addition, the TCJA caused deferred taxes to be reduced using the lower 21% federal tax rate. The impact of the newly enacted 21% corporate income tax rate of the TCJA was a $11.1 million adjustment to the gross deferred tax assets which was offset by the same adjustment to the valuation allowance at December 31, 2017.

4.
Property and equipment

Property and equipment consists of the following:

	March 31, 2018	December 31, 2017

Machines and equipment	$240,295	$240,295
Office and computer equipment	160,982	156,860
Devices	89,704	89,704
Software	38,126	34,528
Furniture and fixtures	16,019	16,019
Other assets	2,259	2,259
Total	547,385	539,665
Accumulated depreciation	(484,312)	(479,296)
Net property and equipment	$63,073	$60,369

Depreciation expense was $5,016 and $6,120 for the three months ended March 31, 2018 and 2017, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2018

5.
Accrued expenses

Accrued expenses consist of the following:

	March 31, 2018	December 31, 2017
Accrued outside services	$187,959	$165,427
Accrued executive severance	122,500	118,000
Accrued travel	54,926	39,926
Accrued audit and tax preparation	53,800	73,800
Accrued board of director's fees	50,000	125,000
Deferred rent	49,968	51,191
Deferred revenue	39,257	13,317
Accrued legal professional fees	32,405	61,890
Accrued clinical study expenses	13,650	13,650
Accrued other	4,391	11,399
	$608,856	$673,600

6.
Contract assets and contract liabilities

As of March 31, 2018, the Company has contract assets from contracts with customers. The contract assets are due to the implementation of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09) (see Note 17).

Contract assets consist of the following:

	March 31, 2018	December 31, 2017
Distribution license	$40,000	$-

Refurbishment license	15,700	-
	$55,700	$-

As of March 31, 2018, the Company has contract liabilities from contracts with customers. The contract liabilities are due to the implementation of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09) (see Note 17).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2018

6.
Contract assets and contract liabilities (continued)

Contract liabilities consist of the following:

	March 31, 2018	December 31, 2017
Distribution license	$54,444	$-
Service agreement	37,553	-
Intitial warranty	13,636	-
Tiered pricing	3,581	-
Total Contract liabilities	109,214	-
Non-Current	(73,374)	-
Total Current	$35,840	$-

Revenue recognized for the three months ended March 31, 2018 and 2017, that was included in deferred revenue balances at the beginning of each period was $2,687 and $12,638, respectively.

7.
Advances from related and unrelated parties

The Company has received cash advances from related parties and accredited investors to help fund the Company's operations. As of March 31, 2018, the Company had received $12,000 from an unrelated party for exercise of warrants. As of December 31, 2017, the Company had received $310,000 from related and unrelated parties as a part of an agreement that the Company offered to issue convertible promissory notes.

As of December 31, 2017, A. Michael Stolarski and Kevin A. Richardson II, both members of the Company's board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The convertible promissory notes for this balance were issued on January 10, 2018 (see Note 8).

8.
Line of credit, related parties

The Company entered into a line of credit agreement with a related party at December 29, 2017. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. The line of credit may be

called for payment upon demand. As of March 31, 2018, no amounts were available for future borrowing under this agreement.

Interest expense on line of credit, related parties totaled $5,550 and $0 for the three months ended March 31, 2018 and 2017, respectively.

9.
Convertible promissory notes

On March 27, 2017, the Company began offering subscriptions for 10% convertible promissory notes (the "10% Convertible Promissory Notes") to selected accredited investors. The Company intends to use the proceeds from the 10% Convertible Promissory Notes for working capital and general corporate purposes. The initial offering closed on August 15, 2017, at which time $55,000 aggregate principal amount of 10% Convertible Promissory Notes were issued and the funds paid to the Company. Subsequent offerings were closed on November 3, 2017, November 30, 2017, December 21, 2017, January 10, 2018 and February 2, 2018 at which times $1,069,440, $199,310, $150,000, $1,496,000 and $100,000 respectively, aggregate principal amounts of 10% Convertible Promissory Notes were issued and the funds paid to the Company. On November 30, 2017, the outstanding balance of $60,000 of a short term loan with Millennium Park Capital LLC was converted into a 10% Convertible Promissory Notes agreement. On January 10, 2018, the outstanding balance of $310,000 of advances from related and unrelated parties was converted into two 10% Convertible Promissory Notes agreements (see Note 7).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2018

9.
Convertible promissory notes (continued)

The 10% Convertible Promissory Notes have a six month term from the subscription date and the note holders can convert the 10% Convertible Promissory Notes at any time during the term to the number of shares of Company common stock, $0.001 par value (the "Common Stock"), equal to the amount obtained by dividing (i) the amount of the unpaid principal and interest on the note by (ii) $0.11.

The 10% Convertible Promissory Notes include a warrant agreement (the "Class N Warrant Agreement") to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount by (ii) $0.11. The Class N Warrant Agreement expires March 17, 2019. On November 3, 2017, the Company issued 10,222,180 Class N Warrants in connection with the initial and second closings of 10% Convertible Promissory Notes. On November 30, 2017, December 21, 2017, January 10, 2018, and February 2, 2018, the Company issued 2,357,364, 1,363,636, 13,599,999 and 909,091 respectively, Class N Warrants in connection with the closings of 10% Convertible Promissory Notes.

Pursuant to the terms of a Registration Rights Agreement (the "Registration Rights Agreement") that the Company entered with the accredited investors in connection with the 10% Convertible Promissory Notes, the Company is required to file a registration statement that covers the shares of Common Stock issuable upon conversion of the 10% Convertible Promissory Notes or upon exercise of the Class N Warrants. The failure on the part of the Company to satisfy certain deadlines described in the Registration Rights Agreement may subject the Company to payment of certain monetary penalties.

In 2018, the Company recorded $709,827 in debt discount for the beneficial conversion feature of the promissory notes, $808,458 in debt discount for the discount on the Class N Warrant agreement and $77,715 in debt issuance costs to be amortized over the lives of the 10% Convertible Promissory Notes. Additional debt issuance costs will be incurred and amortized over the remaining lives of the 10% Convertible Promissory Notes when Class N Warrants are issued per the engagement letter with West Park Capital.

In 2017, the Company recorded $820,681 in debt discount for the beneficial conversion feature of the promissory notes, $620,748 in debt discount for the discount on the Class N Warrant agreement and $89,518 in debt issuance costs to be amortized over the lives of the 10% Convertible Promissory Notes. Additional debt issuance costs will be incurred and amortized over the remaining lives of the 10% Convertible Promissory Notes when Class N Warrants are issued per the engagement letter with West Park Capital.

The 10% Convertible Promissory Notes had an aggregate outstanding principal balance of $1,978,682, net of $1,246,616 beneficial conversion feature, warrant discount and debt issuance costs at March 31, 2018. The 10% Convertible Promissory Notes had an aggregate outstanding principal balance of $455,606, net of $1,099,861 beneficial conversion feature, warrant discount and debt issuance costs at December 31, 2017.

Interest expense on the 10% Convertible Promissory Notes totaled $1,523,076 and $0 for the three months ended March 31, 2018 and 2017, respectively.

A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amounts of $330,000 and $170,000 and was issued

3,000,000 and 1,545,455 Class N Warrants on November 3, 2017 and January 10, 2018, respectively. Kevin A. Richardson II, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $260,000 and was issued 2,363,636 Class N Warrants on January 10, 2018.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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9.
Convertible promissory notes (continued)

On January 29, 2018, the Company entered into a convertible promissory note (the "Convertible Promissory Note") with an accredited investor in the amount of $71,500. The Company intends to use the proceeds from the Convertible Promissory Notes for payment of services to an investor relations company and the account of the attorney updating the Registration Statement on Form S-1 of the Company filed under the Securities Act of 1933, as amended, on January 3, 2017 (File No. 333-213774), which registration statement shall also register the shares issuable upon conversion of the Convertible Promissory Note and issuable upon the exercise of a Class N common stock purchase warrant issued concurrently with the issuance of this Convertible Promissory Note.

The Convertible Promissory Note has a six month term from the subscription date and the note holders can convert the Convertible Promissory Note at any time during the term to the number of shares of Common Stock, equal to the amount obtained by dividing (i) the amount of the unpaid principal and interest on the note by (ii) $0.11.

The Convertible Promissory Note includes a warrant agreement (the "Class N Common Stock Purchase Warrant") to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount by (ii) $0.11. The Class N Common Stock Purchase Warrant expires on March 17, 2019. On January 29, 2018, the Company issued 650,000 Class N Common Stock Purchase Warrants in connection with this Convertible Promissory Note.

The Company recorded $35,396 debt discount for the beneficial conversion feature of the promissory notes and $36,104 in debt discount for the discount on the Class N Warrant agreement to be amortized over the life of the Convertible Promissory Note.

The Convertible Promissory Note had an aggregate outstanding principal balance of $25,859, net of $46,872 beneficial conversion feature, warrant discount and debt issuance costs at March 31, 2018.

Interest expense on the Convertible Promissory Note totaled $25,859 and $0 for the three months ended March 31, 2018 and 2017, respectively.

10.
Note payable, product, related party

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE System in the marketplace. This agreement provides for a lease line of credit up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company's accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company.

On March 1, 2018, the Company entered into the first drawdown of the Master Equipment Lease in the amount of $96,708.

Interest expense on note payable, product totaled $1,270 and $0 for the three months ended March 31, 2018 and 2017, respectively.

As of February 27, 2018, we are in default of Master Equipment Lease due to the sale of equipment purchased under the Master Lease Agreement to a third party and the note is callable by NFS Leasing, Inc or NFS Leasing, Inc. can notify the Company to assemble all equipment for pick up. The notes payable, product is shown as a current liability.

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10.
Notes payable, product, related party (continued)

Minimum future note payments under the note payable, product consist of the following:

Year ending December 31,	Amount
Remainder of 2018	$21,009
2019	31,428
2020	35,832
2021	5,789
Total	$94,058

11.
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 was paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal was originally 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 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 bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. Events of Default under the notes payable, related parties have occurred and are continuing on account of the failure of SANUWAVE, Inc., a Delaware corporation, a wholly owned subsidiary of the Company and the borrower under the notes payable, related parties, to make the required payments of interest which were due on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017, and December 31, 2017 (collectively, the "Defaults"). As a result of the Defaults, the notes payable, related parties have been accruing interest at the rate of 10% per annum since January 2, 2017 and continue to accrue interest at such rate. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company's patents or other intellectual property rights.

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

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

The notes payable, related parties had an aggregate outstanding principal balance of $5,260,243, net of $112,500 debt discount at March 31, 2018 and $5,222,259, net of $150,484 debt discount at December 31, 2017, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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11.
Notes payable, related parties (continued)

In addition, the Company, in connection with the Note Amendment, issued to HealthTronics, Inc. on June 15, 2015, a total of 3,310,000 warrants (the "Class K Warrants") to purchase shares of Common Stock, at an exercise price of $0.55 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after ten years. The fair value of these warrants on the date of issuance was $0.0112 and $36,989 was recorded as a debt discount to be amortized over the life of the amendment.

In addition, the Company, in connection with the Second Amendment, issued to HealthTronics, Inc. on June 28, 2016, an additional 1,890,000 Class K Warrants to purchase shares of the Company's Common Stock at an exercise price of $0.08 per share, subject to certain anti-dilution protection. The exercise price of the 3,310,000 Class K Warrants issued on June 15, 2015 was decreased to $0.08 per share. The fair value of these warrants on the date of issuance was $0.005 and $9,214 was recorded as a debt discount to be amortized over the life of the amendment.

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

Accrued interest currently payable totaled $685,907 at March 31, 2018 and December 31, 2017. Interest expense on notes payable, related parties totaled $189,211 and $140,178 for the three months ended March 31, 2018 and 2017, respectively.

As of January 2, 2017, we are in default with our interest payment and the note is callable by HealthTronics, Inc. The notes payable, related parties are shown as a current liability.

12.
Income taxes

The Company files income tax returns in the United States federal jurisdiction and various state and foreign jurisdictions. The Company is no longer subject to United States federal and state and non-United States income tax examinations by tax authorities for years before 2014.

At March 31, 2018, the Company had federal net operating loss ("NOL") carryforwards for tax years through the year ended December 31, 2017, that will begin to expire in 2025. The use of deferred tax assets, including federal NOLs, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, Income Taxes, the Company's management believes that there is not sufficient evidence at March 31, 2018 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2018. 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.

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13.
Equity transactions

Warrant Exercise

On March 23, 2018, the Company issued 75,666 shares of restricted Common Stock upon the exercise of 75,666 Series A Warrants to purchase shares of stock for $0.0334 per share under the terms of the Series A Warrant agreement.

On February 23, 2018, the Company issued 100,000 shares of restricted Common Stock upon the exercise of 100,000 Class O Warrants to purchase shares of stock for $0.11 per share under the terms of the Class O Warrant agreement.

Cashless Warrant Exercise

On March 28, 2018, the Company issued 84,314 shares of Common Stock upon the cashless exercise of 100,000 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.51 per share as determined under the terms of the Class L Warrant agreement.

On March 2, 2018, the Company issued 407,461 shares of Common Stock upon the cashless exercise of 600,000 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.2493 per share as determined under the terms of the Class L Warrant agreement.

On February 14, 2018, the Company issued 229,515 shares of Common Stock upon the cashless exercise of 400,000 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.1877 per share as determined under the terms of the Class L Warrant agreement.

On March 9, 2018, the Company issued 251,408 shares of Common Stock upon the cashless exercise of 271,000 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.462 per share as determined under the terms of the Series A Warrant agreement.

On January 11, 2018, the Company issued 50,432 shares of Common Stock upon the cashless exercise of 59,000 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.23 per share as determined under the terms of the Series A Warrant agreement.

Consulting Agreement

In November 2017, the Company entered into a three month consulting agreement for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 26,667, 23,529 and 18,182 shares, respectively in each of the three months of the agreement. The $4,000 was recorded as a non-cash general and administrative expense for each of the three months of the agreement.

In May 2017, the Company entered into a consulting agreement for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the

amount of the fee to be paid with Common Stock of $7,500 by the Company's stock price at the close of business on the eighth business day of each month. On March 27, 2018, the Company issued 533,450 shares for services rendered May 2017 through February 2018. Non-cash general and administrative expense of $15,000 and $60,000 was recorded in 2018 and 2017, respectively.

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14.
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.

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.

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15.
Warrants

A summary of the warrant activity as of March 31, 2018 and December 31, 2017, and the changes during the three months ended March 31, 2018, is presented as follows:

Warrant class	Outstanding as of December 31, 2017	Issued	Exercised	Expired	Outstanding as of March 31, 2018
Class F Warrants	300,000	-	-	(300,000)	-
Class G Warrants	1,503,409	-	-	-	1,503,409
Class H Warrants	1,988,095	-	-	-	1,988,095
Class I Warrants	1,043,646	-	-	-	1,043,646
Class K Warrants	7,200,000	-	-	-	7,200,000
Class L Warrants	63,898,173	-	(1,100,000)	-	62,798,173
Class N Warrants	13,943,180	14,509,090	-	-	28,452,270
Class O Warrants	6,540,000	-	(100,000)	-	6,440,000
Series A Warrants	1,561,348	-	(405,666)	-	1,155,682
	97,977,851	14,509,090	(1,605,666)	(300,000)	110,581,275

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

	Exercise price/share	Expiration date
Class G Warrants	$0.80	July 2018
Class H Warrants	$0.80	July 2018

Class I Warrants	$0.85	September 2018
Class K Warrants	$0.08	June 2025
Class K Warrants	$0.11	August 2027
Class L Warrants	$0.08	March 2019
Class N Warrants	$0.11	March 2019
Class O Warrants	$0.11	March 2019
Series A Warrants	$0.03	March 2019

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

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15.
Warrants (continued)

The exercise price of the Class K Warrants and the Series A Warrants are subject to a “down-round” anti-dilution adjustment if the Company issues or is deemed to have issued certain securities at a price lower than the then applicable exercise price of the warrants. The exercise price of the Series A Warrants was adjusted to $0.0334 due to the 2016 Equity Offering. The Class K Warrants may be exercised on a physical settlement or on a cashless basis. The Series A Warrants may be exercised on a physical settlement basis if a registration statement underlying the warrants is effective. If a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale by the holder of the Series A Warrants, then the holder may exercise the warrants on a cashless basis.

In June 2015, the Company, in connection with the Note Amendment (see Note 10), issued to HealthTronics, Inc. an aggregate total of 3,310,000 Class K Warrants to purchase shares of the Company’s common stock, $0.001 par value, at an exercise price of $0.55 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after ten years.

In June 2016, the Company, in connection with the Second Amendment (see Note 10), issued to HealthTronics, Inc., an additional 1,890,000 Class K Warrants to purchase shares of the Company’s Common Stock at an exercise price of $0.08 per share, subject to certain anti-dilution protection. The exercise price of the 3,310,000 Class K Warrants issued on June 15, 2015 was decreased to $0.08 per share. The warrants vested upon issuance and expire after ten years.

In August 2017, the Company, in connection with the Third Amendment (see Note 10), issued to HealthTronics, Inc., an additional 2,000,000 Class K Warrants to purchase shares of the Company’s Common Stock at an exercise price of $0.11 per share, subject to certain anti-dilution protection. The warrants vested upon issuance and expire after ten years.

On November 30, 2017, the Company issued Class O Warrant Agreements to a vendor to purchase 2,500,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $174,731 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019.

On December 6, 2017, the Company issued Class O Warrant Agreements to a vendor to purchase 100,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $8,125 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019.

On December 11, 2017, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $285,810 and was recorded as research and development expense in the amount of $98,655 and general and administrative expense in

the amount of $187,155 and an increase to additional paid-in capital for the full amount of $285,810. The warrants vested upon issuance and expire on March 17, 2019. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company's board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company's board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants as well as other employees of the Company.

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15.
Warrants (continued)

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

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

A summary of the changes in the warrant liability as of March 31, 2018 and December 31, 2017, and the changes during the three months ended March 31, 2018, is presented as follows:

	Class K Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2017	1,616,000	327,883	1,943,883
Issued	-	-	-
Redeemed	-	(118,838)	(118,838)
Change in fair value	2,628,000	345,682	2,973,682
Warrant liability as of March 31, 2018	$4,244,000	$554,727	$4,798,727

16.
Commitments and contingencies

Rent expense for the three months ended March 31, 2018 and 2017, was $35,882 and $33,107, respectively. Minimum future lease payments under the operating lease consist of the following:

Year ending December 31,

	Amount
Remainder of 2018	$104,788
2019	143,318
2020	147,617
2021	152,046
Total	$547,769

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16.
Commitments and contingencies (continued)

Contingency

The Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation and Premier Shockwave, Inc., a Georgia Corporation that contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of Premier Shockwave Wound Care, Inc. have the right and option to cause the Company to purchase all of the stock of Premier Shockwave Wound Care, Inc., and whereby the Company has the right and option to purchase all issued and outstanding shares of Premier Shockwave Wound Care, Inc., in each case based upon certain defined purchase price provisions and other terms.

Litigation

The Company is engaged in various legal actions, claims and proceedings arising in the ordinary course of business, including claims related to breach of contracts and intellectual property matters resulting from our business activities. As with most actions such as these, an estimation of any possible and/or ultimate liability cannot always be determined.

There are no material proceedings known to us to be contemplated by any governmental authority.

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

17.
Revenue

The Company began accounting for revenue in accordance with Topic 606, which we adopted beginning January 1, 2018, using the modified retrospective method. Under the new revenue standard for arrangements that are determined to be within the scope of Topic 606, the Company recognizes revenue when a customer obtains control of the promised goods. To achieve this core principle, we apply the following the five-step model:

1.
Identify the contract(s) with a customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. We do not have significant costs to obtain contracts with customers.
2.
Identify the performance obligation(s) in the contract. Our contracts include multiple performance obligations to be completed. Our performance obligations to deliver medical devices and related components are completed when shipment of these items has been made to the customer. Other performance obligations are completed over a period of time. Limited warranties are provided and extended warranties are offered, under which we typically accept returns

and provide either replacement parts or refunds.

3.

Determine the transaction price. Payment by the customer is due under customary fixed payment terms, and we evaluate if collectability is reasonably assured. The methodology for which we estimate and recognize variable consideration is consistent with the requirements of ASC 606. Revenue is recorded at the net sales prices, which includes estimates of variable consideration such as initial warranty, tiered volume pricing, and other adjustments as noted in customer contracts. The estimates of variable consideration are based on historical and projected sales data and current contract sales terms.

4.

Allocate the transaction price to the performance obligations in the contract. Our contracts include multiple performance obligations to be completed. We recognize revenue upon shipment of medical devices and related components to the customer. We recognize revenue for services over the period of time of the service.

5.

Recognize revenue when (or as) the Company satisfies a performance obligation. We satisfy performance obligations at a point in time upon shipment of goods. We satisfy service related performance obligations over a period of time. Each performance obligation is satisfied in accordance with the terms of each contract with the customer.

There were changes to judgments that affect the determination of the amount and timing of revenue from the adoption of the new guidance. As a result of the adoption of ASC 606, the Company has recorded Contract assets and Contract liabilities. Contract assets primarily represent the difference between the revenue that was earned but not billed on refurbishment license fees and timing difference on revenue from distribution license that is recognized on a straight-line basis but paid in accordance with the terms of the customer contract. Contract liabilities are primarily related to warranties, service contracts, distribution license and tiered volume pricing on medical devices and refurbishment license fee. The revenue recognized under ASC 606 was immaterially different from the revenue recognized under ASC 605.

Disaggregation of Revenue

The disaggregation of revenue is based on type of product and geographical region. The following table presents revenue from contracts with customers for the three months ended March 31, 2018 and 2017:

	Three months ended March 31, 2018			Three months ended March 31, 2017		
	United States	International	Total	United States	International	Total
Devices	$106,447	$33,031	$139,478	$-	$62,210	$62,210
Applicators - new and refurbished	10,000	87,939	97,939	-	72,040	72,040
Distribution license	-	63,334	63,334	-	-	-
License fees	6,250	14,532	20,782	6,250	-	6,250
Warranty and repair	-	10,269	10,269	-	-	-
Other	-	3,452	3,452	-	2,504	2,504
Freight billed	-	9,018	9,018	-	6,565	6,565
	$122,697	$221,575	$344,272	$6,250	$143,319	$149,569

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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18.
Related party transactions

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation (“PSWC”), and Premier Shockwave, Inc., a Georgia Corporation (“PS”). The agreement provides for the purchase by PSWC and PS of dermaPACE System and related equipment sold by the Company and includes a minimum purchase of 100 units over 3 years. The agreement grants PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. Under the agreement, the Company is responsible for the servicing and repairs of such dermaPACE Systems and equipment. The agreement also contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. The agreement also contains certain transfer restrictions on the stock of PSWC. Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company.

During the period ended March 31, 2018, the Company recorded $116,447 in revenue from this related party. The Contract liabilities balance includes a balance of $48,553 and the Accrued expenses balance includes a balance of $10,000 from this related party.

19.
Stock-based compensation

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the “Stock Incentive Plan”). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to three years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At March 31, 2018 and December 31, 2017, the Stock Incentive Plan reserved 22,500,000 shares of common stock for grant.

On June 15, 2017, the Company granted to the active employees, members of the board of directors and members of the Company’s Medical Advisory Board options to purchase 5,550,000 shares each of the Company’s common stock at an exercise price of $0.11 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.0869 resulting in compensation expense of $482,295. Compensation cost was recognized upon grant.

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

	2017
Weighted average expected life in years	5.0
Weighted average risk free interest rate	1.76%
Weighted average volatility	120.00%
Forfeiture rate	0.0%
Expected dividend yield	0.0%

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, $0 for each of the three months ended March 31, 2018 and 2017.

A summary of option outstanding as of March 31, 2018 and December 31, 2017, and the changes during the three months ended March 31, 2018, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding at December 31, 2017	21,593,385	$0.31
Granted	-	$-
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at March 31, 2018	21,593,385	$0.31
Vested and exercisable at March 31, 2018	21,593,385	$0.31

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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19.
Stock-based compensation (continued)

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at March 31, 2018 and December 31, 2017, respectively. The aggregate intrinsic value for all vested and exercisable options was $6,890,735 and $2,073,641 at March 31, 2018 and December 31, 2017, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options was 7.12 and 7.37 years as of March 31, 2018 and December 31, 2017, respectively.

20.
Earnings (loss) per share

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

As a result of the net loss for the three months ended March 31, 2018 and 2017, 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 132,174,660 shares and 92,323,468 shares at March 31, 2018 and 2017, respectively.

21.
Subsequent events

Conversion of 10% Convertible Promissory Notes

On May 9, 2018, the Company issued 5,335,919 shares of restricted common stock upon the conversion of 10% Convertible Promissory Notes in the amount of $571,000 plus accrued interest of $15,951 at the conversion price of $0.11 per share per the 10% Convertible Promissory Notes agreement.

On April 16, 2018, the Company issued 560,808 shares of restricted common stock upon the conversion of 10% Convertible Promissory Notes in the amount of $60,000 plus accrued interest of $1,689 at the conversion price of $0.11 per share per the 10% Convertible Promissory Notes agreement.

Warrant Exercise

On April 20, 2018, the Company issued 227,273 shares of restricted common stock upon the exercise of 227,273 Class N Warrants to purchase shares of stock for $0.11 per share under the terms of the Class N Warrant agreement.

Cashless Warrant Exercise

On April 13, 2018, the Company issued 3,241,395 shares of common stock upon the cashless exercise of 3,733,167 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.6073 per share as determined under the terms of the Class L Warrant agreement.

On April 10, 2018, the Company issued 90,142 shares of common stock upon the cashless exercise of 106,667 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.5164 per share as determined under the terms of the Class L Warrant agreement.

On April 9, 2018, the Company issued 59,020 shares of common stock upon the cashless exercise of 70,000 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.51 per share as determined under the terms of the Class L Warrant agreement.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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21.
Subsequent events (continued)

On April 9, 2018, the Company issued 813,267 shares of common stock upon the cashless exercise of 990,500 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.4471 per share as determined under the terms of the Class L Warrant agreement.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this report, and together with our audited consolidated financial statements, related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as of and for the year ended December 31, 2017 included in our Annual Report on Form 10-K, filed with the SEC on March 29, 2018.

Overview

We are a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. On December 28, 2017, the U.S. Food and Drug Administration (the "FDA") notified the Company to permit the marketing of the dermaPACE System for the treatment of diabetic foot ulcers in the United States.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. In 2018, we have started marketing our dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

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

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

wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;

orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;

plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and

cardiac applications for removing plaque due to atherosclerosis improving heart muscle performance.

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

Recent Developments

On December 28, 2017, the FDA notified the Company to permit the marketing of the dermaPACE system for the treatment of diabetic foot ulcers in the United States.

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

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation ("PSWC"), and Premier Shockwave, Inc., a Georgia Corporation ("PS"). The agreement provides for the purchase by PSWC and PS of dermaPACE System and related equipment sold by the Company and includes a minimum purchase of 100 units over 3 years. The agreement grants PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. Under the agreement, the Company is responsible for the servicing and repairs of such dermaPACE Systems and equipment. The agreement also contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. The agreement also contains certain transfer restrictions on the stock of PSWC. Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company.

Clinical Trials and Marketing

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

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

The dermaPACE device completed its initial Phase III, IDE clinical trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA application was filed with the FDA in July 2011. The patient enrollment for the second, supplemental clinical trial began in June 2013. We completed enrollment for the 130 patients in this second trial in November 2014 and suspended further enrollment at that time.

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

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm2 and 16cm2, inclusive.

Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 – Day 0), the first treatment was applied (either dermaPACE or Sham Control application). Applications with either dermaPACE or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

A total of 336 patients were enrolled in the dermaPACE studies at 37 sites. The patients in the studies were followed for a total of 24 weeks. The studies' primary endpoint, wound closure, was defined as "successful" if the skin was 100% re-epithelialized 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).

At 12 and 24 weeks, the dermaPACE group had a higher percentage of subjects with a 50% wound reduction compared to the control (p=0.0554 and p=0.0899, respectively). Both time points demonstrate a trend towards statistical significance.

The mean wound reduction for dermaPACE subjects at 24 weeks was 2.10cm2 compared to 0.83cm2 in the control group. There was a statistically significant difference between the wound area reductions of the two cohorts from the 6 week follow-up visit through the end of the study.

Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 7.7% in the dermaPACE group compared with 11.6% in the sham-control group.

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

We retained Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in January 2015 to lead the Company’s interactions and correspondence with the FDA for the dermaPACE, which have already commenced. MCRA has

successfully worked with the FDA on numerous Premarket Approvals (PMAs) for various musculoskeletal, restorative and general surgical devices since 2006.

Working with MCRA, we submitted to FDA a de novo petition on July 23, 2016. Due to the strong safety profile of our device and the efficacy of the data showing statistical significance for wound closure for dermaPACE subjects at 20 weeks, we believe that the dermaPACE device should be considered for classification into Class II as there is no legally marketed predicate device and there is not an existing Class III classification regulation or one or more approved PMAs (which would have required a reclassification under Section 513(e) or (f)(3) of the FD&C Act). On December 28, 2017, the FDA determined that the criteria at section 513(a)(1)(A) of (B) of the FD&C Act were met and granted the de novo clearance classifying dermaPACE as Class II and available to be marketed immediately.

Finally, our dermaPACE device has received the European CE Mark approval to treat acute and chronic defects of the skin and subcutaneous soft tissue, such as in the treatment of pressure ulcers, diabetic foot ulcers, burns, and traumatic and surgical wounds. The dermaPACE is also licensed for sale in Canada, Australia, New Zealand and South Korea.

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

Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. We expect to devote substantial resources for the commercialization of the dermaPACE System and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $5,856,655 for the three months ended March 31, 2018 and $5,537,936 for the year ended December 31, 2017. These operating losses create uncertainty about our ability to continue as a going concern.

The continuation of our business is dependent upon raising additional capital during the second and third quarters of 2018 to fund operations. Management's plans are to obtain additional capital in 2018 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 our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

Since our inception, we have incurred losses from operations each year. As of March 31, 2018, we had an accumulated deficit of $110,828,039. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses may continue over the next few years as we prepare for the commercialization of the dermaPACE System for the treatment of diabetic foot ulcers but if we are able to successfully commercialize, market and distribute the dermaPACE System, then we hope to partially or completely offset these losses within the next few years. 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, 2017, filed with the SEC on March 29, 2018.

Critical Accounting Policies and Estimates

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

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

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements filed with our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 29, 2018, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, liabilities related to warrants issued, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

Sales of medical devices, including related applicators and applicator kits, are recognized when shipped to the customer. Shipments under agreements with distributors are invoiced at a fixed price, are not subject to return, and payment for these shipments is not contingent on sales by the distributor. We recognize revenues on shipments to distributors in the same manner as with other customers. The initial warranty and extended warranty on the sale of medical devices will be deferred and recognized over time as the performance obligation is satisfied. Fees from services performed are recognized when the service is performed. License fee for refurbishment of applicators will be recognized at the time the customer is granted the license to refurbish the applicators. Revenue will be calculated using the transaction price that represents the most likely consideration to be received for the license times the number of licenses issued. Fees for upfront distribution license agreements will be recognized on a straight line basis based on the payment schedule in the contract.

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

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. 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.

Liabilities Related to Warrants Issued

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

Warrants Related to Debt Issued

We record a warrant discount related to warrants issued with debt at fair value and recognize the cost using the straight-line method over the term of the related debt as interest expense, which we report in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. We report this warrant discount as a reduction of the related debt liability.

Beneficial Conversion Feature on Convertible Debt

We record a beneficial conversion feature related convertible debt at fair value and recognize the cost using the straight-line method over the term of the related debt as interest expense, which we report in the Other Income (Expense) section in our Consolidated Statements of Comprehensive Loss. We report this beneficial conversion feature as a reduction of the related debt liability.

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

Income Taxes

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, Income Taxes, Accounting for 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, Accounting for Uncertainty in Income Taxes (FIN 48). ASC 740 specifies the way public companies are to account for uncertainties in income tax reporting, and prescribes a methodology for recognizing, reversing, and measuring the tax benefits of a tax position taken, or expected to be taken, in a tax return. ASC 740 requires the evaluation of tax positions taken or expected to be taken in the course of preparing our tax returns to determine whether the tax positions would “more-likely-than-not” be sustained if challenged by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax benefit or expense in the current year.

Results of Operations for the Three Months ended March 31, 2018 and 2017 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended March 31, 2018 were $344,272, compared to $149,569 for the same period in 2017, an increase of $194,703, or 130%. Revenues resulted primarily from sales in the United States and Europe of our dermaPACE and orthoPACE devices and related applicators. The increase in revenues for 2018 was due to first sale of dermaPACE devices and applicators in the United States after obtaining FDA approval and slight increase in refurbishment applicator sales.

Cost of revenues for the three months ended March 31, 2018 were $165,466, compared to $55,144 for the same period in 2017. Gross profit as a percentage of revenues was 52% for the three months ended March 31, 2018, compared to 63% for the same period in 2017. The decrease in gross profit as a percentage of revenues in 2018 was due to higher number of devices sold in 2018, which have a lower gross margin than building new and refurbishing applicators.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2018 were $349,444, compared to $260,338 for the same period in 2017, an increase of $89,106, or 34%. Research and development costs include payments to third parties that relate to our products in clinical development and employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, quality assurance, and research and development departments. The increase in research and development expenses was due to the hiring of a full-time software engineer, accrual of bonus, and a grant given to a university for clinical work to be performed.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2018 were $945,606, as compared to $448,606 for the same period in 2017, an increase of $497,000, or 111%. The increase in general and administrative expenses was due to the hiring of a human resources director, higher travel costs, accrual of bonus, recruiting fees for open positions, higher legal and accounting fees related to SEC filings and higher consultant fees related to the commercialization of dermaPACE.

Other Income (Expense)

Other income (expense) was a net expense of $4,735,395 the three months ended March 31, 2018, as compared to a net income of $127,107 for the same period in 2017, an increase in other expense of $4,862,502. The increase in other expense for 2018 was due to interest expense related to convertible promissory notes and loss on warrant valuation adjustment.

Provision for Income Taxes

At March 31, 2018, we had federal net operating loss carryforwards through the year ended December 31, 2017 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the three months ended March 31, 2018 was $5,856,655, or ($0.04) per basic and diluted share, compared to a net loss of $493,532, or ($0.00) per basic and diluted share, for the same period in 2017, an increase in the net loss of $5,363,123. The increase in the net loss for 2018 was primarily due to higher general and administrative expenses as noted above as well as higher interest expense related to convertible promissory notes and loss on warrant valuation adjustment.

We anticipate that our operating losses will continue over the next few years as we incur expenses related to commercialization of our dermaPACE system for the treatment of diabetic foot ulcers in the United States. If we are able to successfully commercialize, market and distribute the dermaPACE system, we hope to partially or completely offset these losses in the future.

Liquidity and Capital Resources

We expect to devote substantial resources for the commercialization of the dermaPACE System and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $5,856,655for the three months ended March 31, 2018 and $5,537,936 for the year ended December 31, 2017. These operating losses create uncertainty about our ability to continue as a going concern.

At March 31, 2018, the Company's distributor in South Korea accounted for 49% of the total gross outstanding accounts receivable. Due to the political climate and uncertainty in South Korea, this distributor has not been able to finalize its expected sales in late 2016 and 2017 and therefore has been unable to pay the Company in a timely manner. The Company continues to work with the South Korean distributor on a payment plan to get their account current by June 30, 2018.

The continuation of our business is dependent upon raising additional capital during the second and third quarters of 2018 to fund operations. Management's plans are to obtain additional capital in 2018 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.

On December 29, 2017, the Company entered into a line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand. On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE System in the marketplace. This agreement provides for a lease line of up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company's accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company. As of February 27, 2018, we are in default of Master Equipment Lease due to the sale of equipment purchased under the Master Lease Agreement to a third party and the note is callable by NFS Leasing, Inc or NFS Leasing, Inc. can notify the Company to assemble all equipment for pick up.

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

Cash and cash equivalents decreased by $575,979 for the three months ended March 31, 2018 and decreased by $36,033 for the three months ended March 31, 2017. For the three months ended March 31, 2018 and 2017, net cash used by operating activities was $1,848,553 and $114,884, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The increase in the use of cash for operating activities for the three months ended March 31, 2018, as compared to the same period for 2017, of $1,733,669 was primarily due to the increased operating expenses and decreased payables in 2018. Net cash used by investing activities for the three months ended March 31, 2018 consisted of purchase of property and equipment of $7,720. Net cash provided by financing activities for the three months ended March 31, 2018 was $1,279,371 which consisted of $1,159,785 from the issuance of convertible promissory notes, $94,058 net from note payable, product, $13,528 from the exercise of warrants and $12,000 from the advances from related parties for exercise of warrants. Net cash provided by financing activities for the three months ended March 31, 2017 was $77,066 from exercise of warrants.

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 United States, Europe, Canada, Asia and Asia/Pacific.

Contractual Obligations

Our major outstanding contractual obligations relate to our operating lease for our facility, purchase and supplier obligations for product component materials and equipment, and our notes payable, related parties. We have disclosed these obligations in our most recent Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 29, 2018.

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 is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation under the supervision and with the participation of our management, including our Acting Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2018. Based on this evaluation, the Acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not operating effectively as of March 31, 2018. As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 29, 2018, our disclosure controls and procedures were not effective as of December 31, 2017 because of the “material weakness” described below. Such material weaknesses have not yet been fully remediated and continue to impact the effectiveness of our disclosure controls and procedures.

A “material weakness” is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis by the company’s internal controls. As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 29, 2018, as of December 31, 2017, management concluded that we had three material weaknesses in our internal control over financial reporting process. The first material weakness was due to the lack of internal expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distribution agreements. The second material weakness was due to the lack of internal resources to analyze and properly apply generally accepted accounting principle to accounting for equity components of service agreements with select vendors. The third material weakness was due to the lack of internal expertise and resources to ensure that generally accepted accounting principle disclosures are complete and accurate. As a result, management concluded that our internal control over reporting was not effective as of December 31, 2017 and March 31, 2018.

Management believes the material weaknesses identified above were due to the complex and non-routine nature of the Company's complex financial instruments and derivatives and complexity of new sales distribution agreements, as well as lack of internal resources and expertise.

Management's Plan to Remediate Material Weaknesses

Management will develop an updated remediation plan to address the material weaknesses related to its processes and procedures surrounding the accounting for complex financial instruments and derivatives, accounting for complex sales distribution agreements, accounting for equity component of service agreements and ensuring that generally accepted accounting principle disclosures are complete and accurate. The updated remediation plan could consist of, among other things, redesigning the procedures to enhance their identification, capture, review, approval and recording of terms and components of complex financial instruments and derivatives, complex sales distribution agreements, and any equity components of service agreements as well as identify necessary disclosures. Management will research where to obtain additional interpretive guidance on identifying and accounting for these identified areas of material weakness as well as engage, as necessary, an outside consultant to assist in the application of United States GAAP to these areas. The updated remediation plan will be reviewed by the Board of Director's and be implemented upon the board's approval. These measures are intended both to address the identified material weaknesses and to enhance our overall internal control environment.

Changes in Internal Control over Financial Reporting

There have been changes in our internal control over financial reporting that occurred during the period covered by this report that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting. Management is in the process of designing updated changes to its controls as discussed above in "Management's Plan to Remediate Material Weaknesses."

PART II — OTHER INFORMATION

Item 6. EXHIBITS

Exhibit No.	Description
10.1#	Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs of dermaPACE Systems and Equipment among the Company, and Premier Shockwave Wound Care, Inc. and Premier Shockwave, Inc. dated as of February 13, 2018 (Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2018).
10.2	Master Equipment Lease, dated January 26, 2018, by and among the Company and NFS Leasing, Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on February 16, 2018).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Principal Executive Officer.
32.2*	Section 1350 Certification of the Chief Financial Officer.
101.INS*†	XBRL Instance.
101.SCH*†	XBRL Taxonomy Extension Schema.
101.CAL*†	XBRL Taxonomy Extension Calculation.
101.DEF*†	XBRL Taxonomy Extension Definition.
101.LAB*†	XBRL Taxonomy Extension Labels.
101.PRE*†	XBRL Taxonomy Extension Presentation.

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

SIGNATURES

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

SANUWAVE HEALTH, INC.

Dated: May 15, 2018 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)	May 15, 2018
By: /s/ Lisa E. Sundstrom Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	May 15, 2018