SANUWAVE Health, Inc.
Form 10-Q
November 19, 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 September 30, 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 every Interactive Data File required to be submitted 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 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
Emerging growth company

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

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

As of November 9, 2018, there were issued and outstanding 155,533,303 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, operating results, and projected costs; market acceptance of and demand for dermaPACE and our product candidates; management's plans and objectives for future operations; industry trends; regulatory actions that could adversely affect the price of or demand for our approved products; our intellectual property portfolio; our business, marketing and manufacturing capacity and strategy; estimates regarding our capital requirements, the anticipated timing of the need for additional funds, and our expectations regarding future capital-raising transactions, including potential tender offers for certain of our outstanding series of warrants; product liability claims; economic conditions that could adversely affect the level of demand for our products; timing of clinical studies and eventual FDA approval of our products; financial markets; and the competitive environment. 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 compara 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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018	December 31, 2017
ASSETS	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$72,311	$730,184
Accounts receivable, net of allowance for doubtful accounts of $42,950 in 2018 and $92,797 in 2017	152,706	152,520
Inventory	240,973	231,532
Prepaid expenses	168,480	90,288
TOTAL CURRENT ASSETS	634,470	1,204,524
PROPERTY AND EQUIPMENT, net	72,637	60,369
OTHER ASSETS	16,497	13,917
TOTAL ASSETS	$723,604	$1,278,810
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$1,560,965	$1,496,523
Accrued expenses (Note 4)	746,083	673,600
Accrued employee compensation	364,503	1,680
Contract liabilities (Note 5)	353,115	-
Advances payable (Note 6)	144,000	310,000
Line of credit, related parties (Note 7)	524,869	370,179
Convertible promissory notes, net (Note 8)	2,548,325	455,606
Short term notes payable (Note 10)	186,981	-

Accrued interest, related parties (Note 11)	1,005,144	685,907
Warrant liability (Note 13)	1,396,199	1,943,883
Notes payable, related parties, net (Note 11)	5,335,243	5,222,259
TOTAL CURRENT LIABILITIES	14,165,427	11,159,637
NON-CURRENT LIABILITIES		
Contract liabilities (Note 5)	25,959	-
TOTAL NON-CURRENT LIABILITIES	25,959	-
TOTAL LIABILITIES	14,191,386	11,159,637
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 designated; 6,175 shares issued and 0 shares outstanding in 2018 and 2017	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 designated; 293 shares issued and 0 shares outstanding in 2018 and 2017	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 155,107,127 and 139,300,122 issued and outstanding in 2018 and 2017, respectively (Note 12)	155,107	139,300
ADDITIONAL PAID-IN CAPITAL	100,979,533	94,995,040
ACCUMULATED DEFICIT	(114,541,440)	(104,971,384)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(60,982)	(43,783)
TOTAL STOCKHOLDERS' DEFICIT	(13,467,782)	(9,880,827)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$723,604	$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 September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
REVENUES				
Product	$240,759	$143,234	$703,054	$356,911
License fees	335,697	6,250	623,570	36,050
Other revenue	19,333	12,101	66,647	29,238
TOTAL REVENUES	595,789	161,585	1,393,271	422,199
COST OF REVENUES				
Product	151,624	56,415	413,447	105,027
Other	31,970	5,269	102,256	36,496
TOTAL COST OF REVENUES	183,594	61,684	515,703	141,523
GROSS MARGIN	412,195	99,901	877,568	280,676
OPERATING EXPENSES				
Research and development	661,736	266,837	1,379,517	965,084
General and administrative	2,415,106	475,377	5,391,511	1,875,891
Depreciation	5,709	5,465	16,733	17,543
Loss on sale of property and equipment	-	-	3,170	-

TOTAL OPERATING EXPENSES	3,082,551	747,679	6,790,931	2,858,518
OPERATING LOSS	(2,670,356)	(647,778)	(5,913,363)	(2,577,842)
OTHER INCOME (EXPENSE)				
Gain (loss) on warrant valuation adjustment	2,241,008	(41,681)	428,846	316,952
Interest expense	(395,604)	(160,978)	(4,070,326)	(496,997)
Loss on foreign currency exchange	(190)	(888)	(15,213)	(2,907)
TOTAL OTHER INCOME (EXPENSE), NET	1,845,214	(203,547)	(3,656,693)	(182,952)
NET LOSS	(825,142)	(851,325)	(9,570,056)	(2,760,794)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	(6,230)	20,570	(17,199)	6,803
TOTAL COMPREHENSIVE LOSS	$(831,372)	$(830,755)	$(9,587,255)	$(2,753,991)
LOSS PER SHARE:				
Net loss - basic and diluted	$(0.01)	$(0.01)	$(0.06)	$(0.02)
Weighted average shares outstanding - basic and diluted	151,852,757	139,099,843	147,550,321	138,711,527

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(9,570,056)	$(2,760,794)
Adjustments to reconcile loss from continuing operations to net cash used by operating activities		
Depreciation	16,733	17,543
Bad debt expense (recovery)	(49,847)	87,830
Stock-based compensation	2,474,496	482,295
Loss (gain) on warrant valuation adjustment	(428,846)	(316,952)
Amortization of debt issuance costs	2,767,361	-
Amortization of debt discount	112,984	71,298
Stock issued for consulting services	106,500	-
Warrants issued for consulting services	737,457	-
Loss on sale of fixed assets	3,170	-
Accrued interest	280,975	
Changes in assets and liabilities		
Accounts receivable - trade	49,661	200,850
Inventory	(9,441)	55,844
Prepaid expenses	(76,871)	(15,716)
Other	(3,901)	(136)
Accounts payable	184,442	722,467
Accrued expenses	72,483	84,647

Accrued employee compensation	362,823	294
Contract liabilties	379,074	-
Interest payable, related parties	319,237	425,699
NET CASH USED BY OPERATING ACTIVITIES	(2,271,566)	(944,831)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(32,171)	-
NET CASH USED BY INVESTING ACTIVITIES	(32,171)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from convertible promissory notes, net of costs	1,159,785	-
Proceeds from line of credit, related party	280,500	-
Advances from related parties	156,000	751,616
Proceeds from note payable, product	96,708	-
Proceeds from short term note	184,750	-
Proceeds from warrant exercise	38,528	93,067
Payment on line of credit, related party	(144,500)	-
Payments on note payable, product	(96,708)	-
Payments on advances from related parties	(12,000)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,663,063	844,683
EFFECT OF EXCHANGE RATES ON CASH	(17,199)	6,803
NET DECREASE IN CASH AND CASH EQUIVALENTS	(657,873)	(93,345)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	730,184	133,571
CASH AND CASH EQUIVALENTS, END OF PERIOD	$72,311	$40,226
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$151,227	$-
NONCASH INVESTING AND FINANCING ACTIVITIES		
Cashless exercise of warrants	$118,838	$66,966
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 convertible debt	$745,223	$-
Warrants issued for debt	$844,562	$-
Conversion of 10% convertible promissory notes	$831,000	$-

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 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 the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific. The Company generates revenues streams from product sales, licensing transactions and other activities.

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 ("GAAP") 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 GAAP for complete financial statements. The financial information as of September 30, 2018 and for the three and nine months ended September 30, 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 and nine month periods ended September 30, 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.

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 GAAP for complete financial statements. These financial statements should be read in conjunction with the Company's Form 10-K filed with the Securities and Exchange Commission on March 29, 2018.

2. Going Concern

The Company does not currently generate significant recurring revenue and will require additional capital during the fourth quarter of 2018 and the first quarter of 2019. As of September 30, 2018, the Company had an accumulated deficit of $114,541,440 and cash and cash equivalents of $72,311. For the nine months ended September 30, 2018 and 2017, the net cash used by operating activities was $2,271,566 and $944,831, respectively. The Company incurred a net loss of $9,470,056 for the nine months ended September 30, 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 Company's convertible promissory notes (see Note 8) and the notes payable, related parties (see Note 11) indicate substantial doubt about the Company's ability

to continue as a going concern for a period of at least twelve months from the filing of this report.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2018

2. Going Concern (continued)

The continuation of the Company's business is dependent upon raising additional capital during the fourth quarter of 2018 and the first quarter of 2019 to fund operations. Management's plans are to obtain additional capital 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, including through tender offers for the 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 condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

3.
Summary of Significant Accounting Policies

Recently Issued or Adopted Accounting Standards

In May 2014, the Financial Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASC 606), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASC 606 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. ASC 606 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 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 ASC 606 did not have a material impact on its condensed consolidated financial statements; therefore, no cumulative-effect adjustment was recorded on the adoption. 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 Quarterly Report on Form 10-Q (see Notes 5 and 15).

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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 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 makes eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The ASU is effective for fiscal years beginning after December 15, 2017. This standard requires adoption on a retrospective basis unless it is impracticable to apply, in which case it must be applied 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 the Company's financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies what constitutes a modification of a share-based payment award. The ASU is intended to provide clarity and reduce both diversity in practice and cost and complexity when applying the guidance in Topic 718 to a change to the terms or conditions of a share-based payment award. ASU 2017-09 is effective for public entities for annual periods beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not anticipate that the adoption of ASU 2017-09 will have a material impact on its financial condition or results of operations.

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

In June 2018, the FASB issued ASU 2018-07, Compensation – Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting. This ASU simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees. As a result, share-based payments issued to nonemployees related to the acquisition of goods and services will be accounted for similarly to the accounting for share-based payments to employees, with certain exceptions. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within such fiscal years. Early adoption is permitted if financial statements have not yet been issued. The Company is currently evaluating the impact of the adoption of ASU 2018-07 on the Company's financial statements.

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements ("ASU 2018-09"). These amendments provide clarifications and corrections to certain ASC subtopics including the following: Income Statement - Reporting Comprehensive Income – Overall (Topic 220-10), Debt - Modifications and Extinguishments (Topic 470-50), Distinguishing Liabilities from Equity – Overall (Topic 480-10), Compensation - Stock Compensation - Income Taxes (Topic 718-740), Business Combinations - Income Taxes (Topic 805-740), Derivatives and Hedging – Overall (Topic 815- 10), and Fair Value Measurement – Overall (Topic 820-10). The majority of the amendments in ASU 2018-09

will be effective in annual periods beginning after December 15, 2018. The Company is currently evaluating and assessing the impact this guidance will have on its condensed consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10"). The amendments in ASU 2018-10 provide additional clarification and implementation guidance on certain aspects of the previously issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02") and have the same effective and transition requirements as ASU 2016-02. Upon the effective date, ASU 2018-10 will supersede the current lease guidance in ASC Topic 840, Leases. Under the new guidance, lessees will be required to recognize for all leases, with the exception of short-term leases, a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis. Concurrently, lessees will be required to recognize a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASU 2018-10 is effective for emerging growth companies for interim and annual reporting periods beginning after December 15, 2019, with early adoption permitted. The guidance is required to be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative periods presented in the financial statements. The Company is currently assessing the impact this guidance will have on its condensed consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, ("ASU 2018-11"). The amendments in ASU 2018-11 related to transition relief on comparative reporting at adoption affect all entities with lease contracts that choose the additional transition method and separating components of a contract affect only lessors whose lease contracts qualify for the practical expedient. The amendments in ASU 2018-11 are effective for emerging growth companies for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is currently assessing the impact this guidance will have on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements associated with fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2018-13 and its impact on its consolidated financial statements.

4.
Accrued expenses

Accrued expenses consist of the following:

	September 30, 2018	December 31, 2017

Accrued outside services	$194,585	$165,427
Accrued board of director's fees	150,000	125,000
Accrued executive severance	131,500	118,000
Accrued legal and professional fees	119,150	135,690
Accrued travel	69,926	39,926
Deferred rent	46,852	51,191
Accrued clinical study expenses	13,650	13,650
Deferred revenue	10,840	13,317
Accrued other	9,580	11,399
	$746,083	$673,600

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2018

5.
Contract liabilities

As of September 30, 2018, the Company has contract liabilities from contracts with customers, due to the implementation of ASC 606, Revenue from Contracts with Customers (see Note 15).

Contract liabilities consist of the following:

	September 30, 2018	December 31, 2017
Deposit on product	$164,551	$-
Distribution license	141,110	-
Service agreement	40,991	-
Other	32,422	-
Total Contract liabilities	379,074	-
Non-Current	(25,959)	-
Total Current	$353,115	$-

The timing of the Company's revenue recognition may differ from the timing of payment by its customers. A contract asset (receivable) is recorded when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the satisfaction of performance obligations, the Company records a contract liability (deferred revenue) until the performance obligations are satisfied. Of the aggregate $379,074 of contract liability balances as of September 30, 2018, the Company expects to satisfy its remaining performance obligations associated with $353,115 and $25,959 of contract liability balances within the next twelve months and following twelve months, respectively.

Joint Venture

On September 27, 2017, the Company 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 was to 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 were to be 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. Monthly upfront distribution fee payments have been received through May 2018. Through September 30, 2018, the Company received aggregate payments of $372,222. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company received a response letter stating that the Company was in default of the agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. As of September 30, 2018, the Company derecognized the contract assets and contract liabilities associated with the MundiMed contract.

6.
Advances payable

The Company has received cash advances to help fund the Company’s operations. On January 10, 2018, the outstanding balance of the $310,000 of advances payable was converted into two 10% Convertible Promissory Notes (see Note 8). As of September 30, 2018, the Company had balances of $144,000 due to a related party. The advances are non-interest bearing ad have no stated terms. Imputed interest is de minimis to the financial statements.

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).

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7.
Line of credit, related parties

The Company is a party to 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 line of credit is in the amount of $370,000 with an annualized interest rate of 6%. On June 26, 2018, the amount of the line of credit was increased by $280,500. The line of credit may be called for payment upon demand of the holder. As of September 30, 2018, $524,869 was outstanding under the agreement.

Interest expense on the line of credit, related parties totaled $7,590 and $0 for the three months ended September 30, 2018 and 2017, respectively and $18,690 and $0 for the nine months ended September 30, 2018 and 2017, respectively.

8.
Convertible promissory notes

In 2017, the Company began offering subscriptions for 10% convertible promissory notes (the "10% Convertible Promissory Notes") to selected accredited investors. 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. During the nine months ended September 30, 2018, the Company issued $1,596,000 in the aggregate principal amount of 10% Convertible Promissory Notes, including $430,000 purchased by officers and directors.

The 10% Convertible Promissory Notes include a warrant agreement (the "Class N 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 Warrants expire March 17, 2019. On January 10, 2018 and February 2, 2018, the Company issued 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. As of the date of the filing of this report the registration statement has not yet been filed. At this time the monetary penalty has been determine by management to be de minimis.

During the nine months ended September 30, 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. The calculated fair value of the Class N Warrants was determined using the Black-Scholes pricing model based on the following assumptions:

	2018
Weighted average contractual term in years	1.13 - 1.19
Weighted average risk free interest rate	1.98% - 2.15%
Weighted average volatility	94.43% - 98.63%
Forfeiture rate	0.0%
Expected dividend yield	0.0%

On June 29, 2018, the Company issued 1,242,955 Class N Warrants to West Park Capital per the terms of a placement agent agreement and $417,633 was expensed as interest expense.

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8.
Convertible promissory notes (continued)

On February 15, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on August 15, 2017 and began accruing interest at the default interest rate of 18%. On May 3, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on November 3, 2017 and began accruing interest at the default interest rate of 18%. On May 30, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on November 30, 2017 and began accruing interest at the default interest rate of 18%. On June 22, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on December 22, 2017 and began accruing interest at the default interest rate of 18%. On July 10, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on January 10, 2018 and began accruing interest at the default interest rate of 18%. On August 2, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on February 2, 2018 and began accruing interest at the default interest rate of 18%.

On January 29, 2018, the Company entered into an additional 10% Convertible Promissory Note with an accredited investor in the amount of $71,500 and issued 650,000 Class N Warrants in connection with such 10% Convertible Promissory Note. The Company intends to use the proceeds from such 10% Convertible Promissory Note 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 such 10% Convertible Promissory Note and issuable upon the exercise of a Class N Warrants issued concurrently with the issuance of such 10% Convertible Promissory Note.

The Company recorded $35,396 debt discount for the beneficial conversion feature of the 10% Convertible Promissory Note and $36,104 in debt discount for the discount on the Class N Warrant agreement to be amortized over the life of the 10% Convertible Promissory Note.

The 10% Convertible Promissory Note had an aggregate outstanding principal balance of $2,548,325 at September 30, 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.

9.
Notes 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. NFS Leasing Inc. was a purchaser of the 10% Convertible Promissory Notes (see Note 8).

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 $0 for the three months ended September 30, 2018 and $20,909 for the nine months ended September 30, 2018, respectively.

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9.
Notes payable, product, related party (continued)

As of February 27, 2018, we were in default of Master Equipment Lease due to the sale of equipment purchased under the Master Lease Agreement to a third party and, as a result, the note was callable by NFS Leasing, Inc. or NFS Leasing, Inc. could have notified the Company to assemble all equipment for pick up. The notes payable, product was paid in full on June 27, 2018.

10.
Short term notes payable

The Company entered into short term notes payable with six individuals between June 26, 2018 and July 30, 2018 in the total principal amount of $184,750 with an interest rate of 5% per annum. The principal and accrued interest of $186,981 as of September 30, 2018 are due and payable six months from the date of issuance of the respective notes.

11.
Notes payable, related parties

The notes payable, related parties as amended were issued in conjunction with the Company’s purchase of the orthopedic division of HealthTronics, Inc. The notes payable, related parties bear interest at 8% per annum, as amended. All remaining unpaid accrued interest and principal is due on December 31, 2018, as amended. HealthTronics, Inc. is a related party because they are a shareholder in the Company and have a security agreement with the Company detailed below.

On June 15 2015, the Company entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. 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, December 31, 2017, June 30, 2018 and September 30, 2018 (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.

The notes payable, related parties had an aggregate outstanding principal balance of $5,335,243, net of $37,500 debt discount at September 30, 2018 and $5,222,259, net of $150,484 debt discount at December 31, 2017, respectively.

Accrued interest, related parties currently payable totaled $1,005,144 at September 30, 2018 and $685,907 at December 31, 2017. Interest expense on notes payable, related parties totaled $199,991 and $160,979 for the three months ended September 30, 2018 and 2017, respectively, and $583,448 and $444,437 for the nine months ended September 30, 2018 and 2017, respectively.

12.

Equity transactions

Conversion of 10% Convertible Promissory Notes

During the nine months ended September 30, 2018, the Company issued 8,497,238 shares of Common Stock upon the conversion of 10% Convertible Promissory Notes in the amount of $902,500 plus accrued interest of $32,197 at the conversion price of $0.11 per share per the terms of the 10% Convertible Promissory Notes agreement.

Warrant Exercise

During the nine months ended September 30, 2018, the Company issued 402,939 shares of restricted Common Stock upon the exercise of 402,939 Class N Warrants, Series A Warrants and Class O Warrants to purchase shares of stock under the terms of the respective warrant agreements.

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12.
Equity transactions (continued)

Cashless Warrant Exercise

During the nine months ended September 30, 2018, the Company issued 6,283,664 shares of Common Stock upon the cashless exercise of 7,739,425 Class N Warrants, Series A Warrants and Class L Warrants to purchase shares of stock under the terms of the respective warrant agreements.

Consulting Agreement

In April 2018, the Company verbally entered into a month-to-month consulting agreement with a consultant 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 74,714 shares of Common Stock for services performed from January through June 2018. The $20,000 was recorded as a non-cash general and administrative expense upon issuance in June 2018.

On March 27, 2018, the Company issued 533,450 shares of Common Stock for services rendered, pursuant to a consulting agreement, May 2017 through February 2018. On June 28, 2018, the Company issued 15,000 shares of Common Stock for services rendered in March 2018. Non-cash general and administrative expense of $22,500 and $60,000 was recorded in 2018 and 2017, respectively.

13.
Warrants

A summary of the warrant activity during the nine months ended September 30, 2018, is presented as follows:

	Outstanding as of December 31,				Outstanding as of September 30,
Warrant class	2017	Issued	Exercised	Expired	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	-	(6,500,334)	-	57,397,839
Class N Warrants	13,943,180	16,402,045	(1,136,364)	-	29,208,861
Class O Warrants	6,540,000	1,509,091	(100,000)	-	7,949,091
Series A Warrants	1,561,348	-	(405,666)	-	1,155,682
	97,977,851	17,911,136	(8,142,364)	(4,835,150)	102,911,473

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13.
Warrants (continued)

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

	Exercise price/share	Expiration date
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 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. Accordingly, the Company has classified such warrants as derivative liabilities. 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.

During the nine months ended September 30, 2018, the Company granted Class O Warrant Agreements to various vendors to purchase 1,509,091 shares of common stock at an exercise price of $0.11 per share for consulting services rendered. 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 dates totaled $319,885 and was recorded as general and administrative expense and an increase to additional paid-in capital when the warrants were issued. The warrants vested upon issuance and expire on various dates between March 17, 2019 and January 25, 2022.

The Class K Warrants and the Series A 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 have been classified as Level 3 instruments and 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 which ranged from 0.5 to 8.85 years, the volatility of the Company's common stock price which ranged from 112% to 136%, and the risk-free interest rate which ranged from 2.33% to 3.03%. In addition, as of the valuation dates, management assessed the probabilities of future financing and other re-pricing events in the binominal valuation models.

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13.
Warrants (continued)

A summary of the changes in the warrant liability during the nine months ended September 30, 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	(412,800)	(16,046)	(428,846)
Warrant liability as of September 30, 2018	$1,203,200	$192,999	$1,396,199

14.
Commitments and contingencies

Operating Leases

The Company is a party to certain operating leases. Rent expense for the three months ended September 30, 2018 and 2017 was $36,755 and $33,572, respectively and for the nine months ended September 30, 2018 and 2017 was $108,776 and $99,800, respectively. Minimum future lease payments under the operating lease consist of the following:

Year ending December 31,	Amount
2018 (remainder)	$35,387
2019	143,318
2020	147,617
2021	152,046
Total	$478,368

Litigation

The Company is a defendant 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. We believe that all pending claims, if adversely decided, would not have a material adverse effect on our business, financial position or results of operations.

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15.
Revenue

The Company began accounting for revenue in accordance with ASC 606, which we adopted beginning January 1, 2018, using the modified retrospective method (see Note 3). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. As a result of the adoption of ASC 606, the Company has recorded contract assets and contract liabilities (see Note 5).

Pursuant to ASC 606, 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.
2.
Identify the performance obligation(s) in the contract. If a contract promises to transfer more than one good or service to a customer, each good or service constitutes a separate performance obligation if the good or service is distinct or capable of being distinct.
3.
Determine the transaction price. The transaction price is the amount of consideration to which the entity expects to be entitled in exchanging the promised goods or services to the customer.
4.
Allocate the transaction price to the performance obligations in the contract. For a contract that has more than one performance obligation, an entity should allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which an entity expects to be entitled in exchange for satisfying each performance obligation.
5.
Recognize revenue when (or as) the Company satisfies a performance obligation. For each performance obligation, an entity should determine whether the entity satisfies the performance obligation at a point in time or over time. Appropriate methods of measuring progress include output methods and input methods.

The Company recognizes revenue primarily from the following types of contracts:

Product sales

Product sales include devices and applicators (new and refurbished). Product sales revenue is recognized at the point in time where the customer obtains control of the goods and the Company satisfies its performance obligation, which is generally at the time the Company ships the product to the customer.

Licensing transactions

Licensing transaction include distribution licenses and intellectual property licenses. The Company’s licenses are primarily symbolic licenses, with no significant stand-alone functionality. Symbolic licensing fee revenue is recognized over the time period that the Company satisfies its performance obligations, which is generally the term of the licensing agreement.

Other activities

Other activities primarily include warranties, repairs and billed freight. Device product sales are bundled with an initial one-year warranty and the Company offers a separately priced second-year warranty. The Company allocates the device sales price to the product and the embedded warranty by reference to the stand-alone extended warranty price. Because the warranty represents a stand-ready obligation, revenue is recognized over the time period that the Company satisfies its performance obligations, which is generally the warranty term. Repairs (parts and labor) and billed freight revenue are recognized at the point in time that the service is performed, or the product is shipped, respectively.

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15.
Revenue (continued)

Disaggregation of Revenue

The disaggregation of revenue is based on geographical region. The following table presents revenue from contracts with customers for the three and nine months ended September 30, 2018 and 2017:

	Three months ended September 30, 2018			Three months ended September 30, 2017		
	United States	International	Total	United States	International	Total
Product	$5,891	$234,868	$240,759	$-	$143,234	$143,234
License fees	6,250	329,447	335,697	6,250	-	6,250
Other Revenue	-	19,333	19,333	-	12,101	12,101
	$12,141	$583,648	$595,789	$6,250	$155,335	$161,585

	Nine months ended September 30, 2018			Nine months ended September 30, 2017		
	United States	International	Total	United States	International	Total
Product	$141,231	$561,823	$703,054	$-	$356,911	$356,911
License fees	18,750	604,820	623,570	18,750	17,300	36,050
Other Revenue	-	66,647	66,647	-	29,238	29,238
	$159,981	$1,233,290	$1,393,271	$18,750	$403,449	$422,199

Management routinely assesses the financial strength of its customers and, as a consequence, believes accounts receivable are stated at the net realizable value and credit risk exposure is limited. Five distributors accounted for 7%, 24%, 20%, 9% and 27% of revenues for the nine months ended September 30, 2018, and 0%, 60%, 0%, 0% and 6% of accounts receivable at September 30, 2018. Three distributors accounted for 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017.

16.
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 September 30, 2018, the Company recorded $141,231 in revenue from this related party. The Contract liabilities balance includes a balance of $47,791 and the Accrued expenses balance includes a balance of $154,500 from this related party.

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17.
Stock-based compensation

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Stock Incentive Plan"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to three years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At September 30, 2018, the Stock Incentive Plan reserved 35,000,000 shares of common stock for grant and 4,658,281 shares are available for issuance.

During the nine months ended September 30, 2018, the Company granted to employees, members of the board of directors and members of the Company's Medical Advisory Board options to purchase an aggregate of 10,080,000 shares of common stock under a previously issued incentive plan. The options have an exercise price between $0.11 and $0.42 per share for an aggregate grant date value of $2,474,496. The options vested upon issuance and have a term of ten years.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the nine months ended September 30, 2018 and 2017:

	2018	2017
Weighted average expected life in years	5.0	5.0
Weighted average risk free interest rate	3.02%	1.76%
Weighted average volatility	141.87%	120.00%
Forfeiture rate	0.0%	0.0%
Expected dividend yield	0.0%	0.0%

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, $1,637,700 and $0 for the three months ended September 30, 2018 and 2017, respectively, and $2,474,496 and $482,295 for the nine months ended September 30, 2018 and 2017, respectively, as a component of operating expenses. As of September 30, 2018, there is no unamortized compensation expense for unvested options.

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17.
Stock-based compensation (continued)

A summary of option outstanding as of September 30, 2018 and December 31, 2017, and the changes during the three months ended March 31, 2018, June 30, 2018 and September 30, 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
Granted	2,130,000	$0.41
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at June 30, 2018	23,723,385	$0.32
Granted	7,950,000	$0.21
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at September 30, 2018	31,673,385	$0.29
Vested and exercisable at September 30, 2018	31,673,385	$0.29

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at September 30, 2018 and December 31, 2017, respectively. The aggregate intrinsic value for all vested and exercisable options was $1,456,116 and $2,073,641 at September 30, 2018 and December 31, 2017, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options was 7.65 and 7.37 years as of September 30, 2018 and December 31, 2017, respectively.

18.
Earnings (loss) per share

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. To the extent that securities are “anti-dilutive,” they are excluded from the calculation of diluted net income (loss) per share.

As a result of the net loss for the nine months ended September 30, 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 158,075,531 shares and 99,388,222 shares at September 30, 2018 and 2017, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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19.
Subsequent events

The Company evaluates events that have occurred after the balance sheet date but before the financial statements are issued.

Short term notes payable – related party

On October 10, 2018, the Company entered into short term notes payable with Shri P. Parikh, the President of the Company, in the total principal amount of $100,000 with an interest rate of 5% per annum. The principal and accrued interest are due and payable on the earlier of (i) one day after receipt of payment from Johnfk Medical Inc. and (ii) six months from the date of issuance and (iii) the acceleration of the maturity of the short term note by the holder upon the occurrence of an event of default.

Consulting agreement

On October 17, 2018, the Company and a vendor agreed to settle a portion of a previously incurred fee for services in Common Stock in lieu of cash. On October 17, 2018, the Company issued 426,176 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.

Line of credit – related parties

On November 12, 2018, the Company entered into an amendment to the 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 line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder. On October 5, 2018 and October 23, 2018, the Company received $15,000 and $40,000, respectively, as an increase in the line of credit.

Short term notes payable

On November 8, 2018, the Company entered into short term notes payable with five individuals in the total principal amount of $306,000 with an interest rate of 10% per annum. The principal and accrued interest are due and payable six months from the date of issuance or receipt of notice of warrant exercise.

Joint venture incorporated

On November 9, 2018, the joint venture entity with Johnfk Medical Inc. ("FKS") was incorporated in the Republic of Singapore with the name of Holistic Wellness Alliance Pte. Ltd. (“HWA”). The Company previously was a party to a distribution and licensing agreement with FKS. HWA was formed as a joint venture of the Company and FKS for the manufacture, sale and distribution of the Company’s dermaPACE® and orthoPACE® devices. Under the JV Agreement, the Company and FKS each hold shares constituting fifty percent of the issued share capital of HWA. The Company provides to HWA FDA and CE approved products for an agreed cost, access to treatment protocols, training, marketing and sales materials and management expertise, and FKS provides to HWA capital, human capital

and sales resources in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam, certain reports and identification of new key opinion leaders as well as clinical trial and poster access availability. The JV Agreement also established the corporate governance of HWA, including a five-person board of directors consisting of two directors designated by the Company, two directors designated by FKS, and a third director appointed jointly by the parties.

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. Monthly upfront distribution fee payments have been received through May 2018. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company recieved a response letter stating that the Company was in default of teh agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. The Companh is currently in discussions with a new partner to take over this agreement for the marketing and distibution of its products in Brazil.

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.

On June 26, 2018, the Company entered into an Agreement with Johnfk Medical Inc. ("FKS"), effective as of June 14, 2018, pursuant to which the Company and FKS committed to enter into a joint venture for the manufacture, sale and distribution of the Company's dermaPACE and orthoPACE devices. Under the Agreement, FKS paid the Company a fee of $500,000 for initial distribution rights in Taiwan on June 22, 2018, with an additional fee of $500,000 for initial distribution rights in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam (the "SEA Region") to be paid in the fourth quarter of 2018. On September 21, 2018, the Company entered into a joint venture agreement (the "JV Agreement") with FKS setting forth the terms of the operation, management and control of a joint venture entity initially with the name of Holistic Health Institute Pte. Ltd., a private limited company to be incorporated in the Republic of Singapore, but with such company name subject to confirmation by Singapore Government. On November 9, 2018, the joint venture entity was incorporated in the Republic of Singapore with the name of Holistic Wellness Alliance Pte. Ltd. ("HWA"). HWA was formed as a joint venture of the Company and FKS for the manufacture, sale and distribution of the Company's dermaPACE® and orthoPACE® devices. Under the JV Agreement, the Company and FKS each hold shares constituting fifty percent of the issued share capital of HWA. The Company provides to HWA FDA and CE approved products for an agreed cost, access to treatment protocols, training, marketing and sales materials and management expertise, and FKS provides to HWA capital, human capital and sales resources in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam, certain reports and identification of new key opinion leaders as well as clinical trial and poster access availability. The JV Agreement also established the corporate governance of HWA, including a five-person board of directors consisting of two directors designated by the Company, two directors designated by FKS, and a third director appointed jointly by the parties. Initially, net profits under the JV Agreement shall be used to repay FKS for (i) the

payment of $500,000 on June 22, 2018 to the Company for initial distribution rights in Taiwan and (ii) the cash advance to HWA per the terms of the JV Agreement. The JV Agreement includes other customary terms, including regarding the transfer of shares, indemnification and confidentiality.

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 our inception, we have incurred losses from operations each year. As of September 30, 2018, we had an accumulated deficit of $114,541,440. Although the size and timing of our future operating losses are subject to significant uncertainty, 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.

Our operating losses create substantial doubt about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing will provide the necessary funding for us to continue as a going concern for the next year. See "Liquitiy and Capital Resources" for furher information regarding our fianncial condition.

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 and marketing 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 channels and partnerships, including our efforts to expand our marketing, sales and distribution reach through joint ventures and other contractual arrangements;

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 condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our condensed 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.

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.

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.

Results of Operations for the Three Months ended September 30, 2018 and 2017 (Unaudited)

Revenues and Cost of Revenues

Revenues for the three months ended September 30, 2018 were $595,789, compared to $161,585 for the same period in 2017, an increase of $434,204, or 269%. Revenues resulted primarily from higher sales in Southeast Asia and Europe of our dermaPACE and orthoPACE devices and related applicators. In addition, revenues for 2018 include revenue recognized per Topic 606 from distribution licensing agreement in Southeast Asia with our joint venture partner, FKS.

Cost of revenues for the three months ended September 30, 2018 were $183,594, compared to $61,684 for the same period in 2017. Gross profit as a percentage of revenues was 69% for the three months ended September 30, 2018, compared to 62% for the same period in 2017. The increase in gross profit as a percentage of revenues in 2018 was mainly due to revenue from distribution licensing agreements have zero cost.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2018 were $661,736, compared to $266,837 for the same period in 2017, an increase of $394,899, or 148%. 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 higher salary and benefit expenses related to new hires, accrual of bonus, stock-based compensation expense related to stock options issued in September 2018 and higher travel costs.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2018 were $2,415,106, as compared to $475,377 for the same period in 2017, an increase of $1,939,729, or 408%. The increase in general and administrative expenses was due to increased headcount, stock-based compensation expense related to stock options issued in September 2018, higher travel costs, accrual of bonus, and higher consultant fees related to the commercialization of dermaPACE.

Other Income (Expense)

Other income (expense) was a net income of $1,845,214 the three months ended September 30, 2018, as compared to a net expense of $203,547 for the same period in 2017, an increase in other income (expense) of $2,048,761. The increase in other income (expense) for 2018 was mainly due to gain on warrant valuation adjustment due to the decrease in stock price that was partially offset by an increase in interest expense related to convertible promissory notes.

Net Loss

Net loss for the three months ended September 30, 2018 was $825,142, or ($0.01) per basic and diluted share, compared to a net loss of $851,325, or ($0.01) per basic and diluted share, for the same period in 2017, a decrease in the net loss of $26,183. The decrease in the net loss for 2018 was primarily due to gain on warrant valuation adjustment which was partially offset by higher general and administrative expenses as noted above as well as higher interest expense related to convertible promissory notes.

Results of Operations for the Nine Months ended September 30, 2018 and 2017 (Unaudited)

Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2018 were $1,393,271, compared to $422,199 for the same period in 2017, an increase of $971,072, or 230%. 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 the higher sale of devices and both new and refurbished applicators in the United States, Southeast Asia and Europe as compared to the same period in 2017.

Cost of revenues for the nine months ended September 30, 2018 were $515,703, compared to $141,523 for the same period in 2017. Gross profit as a percentage of revenues was 63% for the nine months ended September 30, 2018, compared to 66% for the same period in 2017. The decrease in gross profit as a percentage of revenues in 2018 was due to the 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 nine months ended September 30, 2018 were $1,379,517, compared to $965,084 for the same period in 2017, an increase of $414,433, or 43%. 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 increased salary and benefits related to new hires, stock-based compensation expense for stock options issued to new hires and in September 2018, accrual of bonus, and consulting fees related to reimbursement strategy which was partially offset by lower consultant costs related to the FDA submission and follow up.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2018 were $5,391,511, as compared to $1,875,891 for the same period in 2017, an increase of $3,515,620, or 187%. The increase in general and administrative expenses was due to the hiring of a president and human resources director and the related stock-based compensation expense for stock options issued, stock-based compensation for options issued in September 2018, 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 $3,656,693 the nine months ended September 30, 2018, as compared to a net expense of $182,952 for the same period in 2017, an increase in other expense of $3,473,741. The increase in other expense for 2018 was mainly due to interest expense related to convertible promissory notes and notes payable, related party and was partially offset by a gain on warrant valuation adjustment.

Net Loss

Net loss for the nine months ended September 30, 2018 was $9,570,056, or ($0.06) per basic and diluted share, compared to a net loss of $2,760,794, or ($0.02) per basic and diluted share, for the same period in 2017, an increase in the net loss of $6,809,262. 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.

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 $9,570,056 for the nine months ended September 30, 2018 and $5,537,936 for the year ended December 31, 2017. These operating losses create substantial doubt about our ability to continue as a going concern.

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities.

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%. On June 21, 2018, the Company made a payment of $144,500 on the line of credit. On June 26, 2018, the amount of the line of credit was increased by $280,500. The line of credit may be called for payment upon demand.

On November 12, 2018, the Company entered into an amendment to the 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 line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder. On October 5, 2018 and October 23, 2018, the Company received $15,000 and $40,000, respectively, as an increase in the line of credit.

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. (“NFS”) 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 were in default of Master Equipment Lease due to the sale of equipment purchased under the Master Lease Agreement to a third party and, as a result, the note is callable by NFS or NFS. could have notified the Company to assemble all equipment for pick up. The Master Equipment Lease was paid in full on June 27, 2018.

On June 26, 2018, the Company entered into an agreement with Johnfk Medical Inc. ("FKS"), effective as of June 14, 2018, pursuant to which the Company and FKS committed to enter into a joint venture for the manufacture, sale and distribution of the Company's dermaPACE and orthoPACE devices. On September 21, 2018, the Company entered into a joint venture agreement with FKS setting forth the terms of the operation, management and control of a joint venture entity initially with the name of Holistic Health Institute Pte. Ltd., a private limited company to be incorporated in the Republic of Singapore, but with such company name subject to confirmation by Singapore Government. On November 9, 2018, the joint venture entity was incorporated in the Republic of Singapore with the name of Holistic Wellness Alliance Pte. Ltd. Under the terms of the June 2018 agreement, FKS paid the Company a fee of $500,000 on June 22, 2018 for initial distribution rights in Taiwan. We expect to receive an additional fee of $500,000 for initial distribution rights in the SEA Region in the fourth quarter of 2018 under the June 2018 agreement.

During the past two quarters, we have also entered into short term notes payable with various individuals to fund our operations. As of September 30, 2018, we had entered into short term notes payable in the principal amount of $184,750, each with an interest rate of 5% per annum and with principal and accrued interest due and payable six months from the date of issuance. On October 10, 2018, we entered into short term notes payable with Shri P. Parikh, the President of the Company, in the total principal amount of $100,000 with an interest rate of 5% per annum. The principal and accrued interest are due and payable on the earlier of (i) one day after receipt of payment from FKS, (ii) six months from the date of issuance and (iii) the acceleration of the maturity of the short term note by the holder upon the occurrence of an event of default. On Novmeber 8, 2018, the Company entered into short term notes payable with two individuals in the total principal amount of $160,667 with an interest rate of 10% per annum. The principal and accrued interest are due and payable six months from the date of issuance or receipt of notice of warrant exercise.

The continuation of our business is dependent upon raising additional capital during the fourth quarter of 2018 and the first quarter of 2019 to fund operations. Management's plans are to obtain additional capital 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, including through tender offers for the 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.

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.

In addition, we may have potential liability for certain issuances of shares of Common Stock in possible violation of federal securities laws. The issuance of shares of Common Stock underlying certain of our warrants may have been in violation of the Section 5 of the Securities Act and the rules and regulations under the Securities Act. Eligible warrantholders have not filed a claim against the Company alleging a violation of the Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of the Section 5 of the Securities Act did in fact occur,

eligible warrantholders, which the Company estimates represents fewer than 10 warrantholders, would have a right to rescind their exercises of warrants and the Company may have to refund any cash amounts paid for such exercises, which could have a materially adverse effect on the Company's financial condition.

Cash and cash equivalents decreased by $657,873 for the nine months ended September 30, 2018 and decreased by $93,345 for the nine months ended September 30, 2017. For the nine months ended September 30, 2018 and 2017, net cash used by operating activities was $2,271,566 and $944,831, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The increase of $1,326,735 in the use of cash for operating activities for the nine months ended September 30, 2018, as compared to the same period for 2017, was primarily due to the increased operating expenses and increased receivables in 2018. Net cash used by investing activities for the nine months ended September 30, 2018 consisted of purchase of property and equipment of $32,171. Net cash provided by financing activities for the nine months ended September 30, 2018 was $1,663,063, which consisted of $1,159,785 from the issuance of convertible promissory notes, $38,528 from the exercise of warrants, $136,000 net increase in line of credit, $184,750 from the issuance of short term notes payable and $144,000 from an advance from related party. Net cash provided by financing activities for the nine months ended September 30, 2017 was $844,683, which consisted of $751,616 from advances from related parties and $93,067 from exercise of warrants.

Segment and Geographic Information

We have determined that we have one operating segment. Our revenues are generated from sales in United States, Europe, Canada, Asia and Asia/Pacific. All significant expenses are generated in the United States and all significant assets are located in the United States.

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 September 30, 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 September 30, 2018 because of the “material weaknesses” 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, management concluded that as of December 31, 2017 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. All three of these material weaknesses continue to exist as of September 30, 2018. As a result, management concluded that our internal control over reporting was not effective as of September 30, 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 1. LEGAL PROCEEDINGS.

For a description of our material legal proceedings, see "Litigation" in Note 17—"Commitments and Contingencies" in the notes to our condensed consolidated financial statements, which is incorporated herein by reference.

Item 1A. Risk Factors.
As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information required under this item.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
Not applicable.

Item 3. Defaults Upon Senior Securities.
Not applicable.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.
Not applicable.

Item 6. EXHIBITS

Exhibit No.	Description
10.1	Joint Venture Agreement, dated September 21, 2018, by and among the Company,m Johnfk Medical Inc. and Holistic Wellness Alliance Pte. Ltd. (formerly known as Holistic Health Institute Pte. Ltd.) (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on September 27, 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.

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* Filed herewith.
** Furnished herewith.
† XBRL-related documents are not deemed filed for purposes of section 11 of the Securities Act of 1933, as amended, section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject the liabilities of these sections, and are not part of any registration statement to which they relate.

SIGNATURES

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

SANUWAVE HEALTH, INC.

Dated: November 19, 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)	November 19, 2018
By: /s/ Lisa E. Sundstrom Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	November 19, 2018