SECURITIES & EXCHANGE COMMISSION EDGAR FILING

SANUWAVE Health, Inc.

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File No. 333-232170

Prospectus Supplement No. 1
(To Prospectus dated June 28, 2019, as previously amended)

SANUWAVE HEALTH, INC.

76,204,992 Shares
(Common Stock, $0.001 par value)

This prospectus supplement supplements the prospectus dated June 28, 2019, as previously amended (the "Prospectus"), related to the resale of up to 76,204,992 shares of our common stock, par value $0.001 ("Common Stock") being offered by the selling stockholders named in the Prospectus. The shares consist of (i) 8,528,249 shares of Common Stock issued upon the conversion of certain promissory notes held by such selling stockholders, (ii) 26,666,487 shares of Common Stock issuable upon the conversion of certain promissory notes held by such selling stockholders, (iii) 3,803,932 shares of Common Stock issued upon the exercise of certain warrants held by such selling stockholders, (iv) 22,124,998 shares of Common Stock issuable upon the exercise of certain warrants held by such selling stockholders, (v) 182,217 shares of Common Stock issued upon exercise of certain warrants issued to the placement agent for the private placements described in the Prospectus, (vi) 2,089,317 shares of Common Stock issuable upon exercise of certain warrants issued to the placement agent for the private placements described in the Prospectus, (vii) 8,049,091 shares of Common Stock issuable upon the exercise of certain warrants issued to employees, board of directors, medical advisory board members and vendors and (viii) 4,760,701 shares of Common Stock issuable upon the conversion of short term notes payable held by such selling stockholders. The shares offered by the Prospectus may be sold by the selling stockholders from time to time in the over-the-counter market or any other national securities exchange or automated interdealer quotation system on which our Common Stock is then listed or quoted, through negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, as described under "Plan of Distribution" in the Prospectus. This prospectus supplement should be read in conjunction with the Prospectus.

This prospectus supplement contains the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 filed by the Company with the Securities and Exchange Commission on August 14, 2019 (the "10-Q"). The 10-Q is set forth below. This prospectus supplement is not complete without, and may not be delivered or used except in connection with, the Prospectus. This prospectus supplement is qualified by reference to the Prospectus except to the extent that the information in this prospectus supplement updates and supersedes the information contained in the Prospectus.

Our common stock is quoted on the OTC Bulletin Board under the symbol SNWV.QB. On August 12, 2019, the last reported sale price of our common stock on the OTC Bulletin Board was $0.12 per share.

Investing in our common stock involves a high degree of risk.
See Risk Factors beginning on page 8 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is August 15, 2019.

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

FORM 10-Q

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

For the quarterly period ended June 30, 2019

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to

Commission File Number 000-52985

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	SNWV	OTCQB

As of August 9, 2019, there were issued and outstanding 195,892,098 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 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing agreements, or raising capital through the conversion of outstanding warrants or issuances of securities; 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; the competitive environment; and our plans to remediate our material weaknesses in our disclosure controls and procedures and our internal control over financial reporting. These forward-looking statements are based on management's estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" and "continue," the negative of these terms, or other comparable terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission (the "SEC"), specifically the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed on April 1, 2019 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, 2018, filed on April 1, 2019.

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

	June 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
CURRENT ASSETS		
Cash and cash equivalents	$ 154,446	$ 364,549
Accounts receivable, net of allowance for doubtful accounts of $58,293 in 2019 and $33,045 in 2018	175,041	234,774
Due from related parties	-	1,228
Inventory	423,932	357,820
Prepaid expenses and other current assets	251,616	125,111
TOTAL CURRENT ASSETS	1,005,035	1,083,482
PROPERTY AND EQUIPMENT, net	85,782	77,755
RIGHT OF USE ASSETS	398,698	-
OTHER ASSETS	23,561	16,491
TOTAL ASSETS	$ 1,513,076	$ 1,177,728
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$ 1,456,727	$ 1,592,643
Accrued expenses	795,458	689,280
Accrued employee compensation	865,900	340,413
Contract liabilities	114,814	131,797
Lease liability - right of use	167,437	-
Advances from related parties	585,022	-
Line of credit, related parties	726,009	883,224
Accrued interest, related parties	1,504,453	1,171,782
Short term notes payable	3,079,767	1,883,163
Convertible promissory notes, net	2,860,478	2,652,377
Notes payable, related parties, net	5,372,743	5,372,743
Warrant liability	-	1,769,669
TOTAL CURRENT LIABILITIES	17,528,808	16,487,091
NON-CURRENT LIABILITIES		
Contract liabilities	67,361	46,736
Lease liability - right of use	272,413	-
TOTAL NON-CURRENT LIABILITIES	339,774	46,736
TOTAL LIABILITIES	17,868,582	16,533,827
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 2019 and 2018	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 designated; 293 shares issued and 0 shares outstanding in 2019 and 2018	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 188,650,891 and 155,665,138 issued and outstanding in 2019 and 2018, respectively	188,651	155,665
ADDITIONAL PAID-IN CAPITAL	103,774,485	101,153,882
ACCUMULATED DEFICIT	(120,254,865)	(116,602,778)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(63,777)	(62,868)
TOTAL STOCKHOLDERS' DEFICIT	(16,355,506)	(15,356,099)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 1,513,076	$ 1,177,728

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

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

	Three Months Ended June 30, 2019	Three Months Ended June 30, 2018	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
REVENUES				
Product	$ 220,667	$ 243,465	$ 285,232	$ 482,033
License fees	66,808	203,757	173,058	287,873
Other revenue	29,501	5,988	36,649	27,576
TOTAL REVENUES	316,976	453,210	494,939	797,482
COST OF REVENUES				
Product	178,458	128,716	243,570	254,309
Other	7,423	37,927	36,164	77,800
TOTAL COST OF REVENUES	185,881	166,643	279,734	332,109
GROSS MARGIN	131,095	286,567	215,205	465,373
OPERATING EXPENSES				
Research and development	307,273	328,753	567,922	678,197
Selling and marketing	407,477	158,695	565,559	210,654
General and administrative	1,426,405	1,911,688	2,943,860	2,805,335
Depreciation	9,455	6,008	17,812	11,024
Loss on sale of property and equipment	-	3,170	-	3,170
TOTAL OPERATING EXPENSES	2,150,610	2,408,314	4,095,153	3,708,380
OPERATING LOSS	(2,019,515)	(2,121,747)	(3,879,948)	(3,243,007)
OTHER INCOME (EXPENSE)				
Gain (loss) on warrant valuation adjustment	195,310	1,161,520	227,669	(1,812,162)
Interest expense	(790,178)	(1,735,509)	(938,439)	(3,291,265)
Interest expense, related party	(112,984)	(194,246)	(332,671)	(383,457)
Gain (loss) on foreign currency exchange	(7,064)	1,723	(8,359)	(15,023)
TOTAL OTHER INCOME (EXPENSE), NET	(714,916)	(766,512)	(1,051,800)	(5,501,907)
NET LOSS	(2,734,431)	(2,888,259)	(4,931,748)	(8,744,914)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	1,489	(11,904)	(909)	(10,969)
TOTAL COMPREHENSIVE LOSS	$ (2,732,942)	$ (2,900,163)	$ (4,932,657)	$ (8,755,883)
LOSS PER SHARE:				
Net loss - basic and diluted	$ (0.02)	$ (0.02)	$ (0.03)	$ (0.06)
Weighted average shares outstanding - basic and diluted	174,730,747	148,582,386	165,921,811	144,168,215

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(UNAUDITED)

	Preferred Stock		Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balances as of January 1, 2018	-	$ -	139,300,122	$ 139,300	$ 94,995,040	$ (104,971,384)	$ (43,783)	$ (9,880,827)
Net loss	-	-	-	-	-	(5,856,655)	-	(5,856,655)
Cashless warrant exercises	-	-	1,023,130	1,023	117,815	-	-	118,838
Proceeds from warrant exercise	-	-	175,666	176	13,352	-	-	13,528
Shares issued for services	-	-	551,632	552	78,448	-	-	79,000
Warrants issued with convertible promissory notes	-	-	-	-	808,458	-	-	808,458
Beneficial conversion feature on convertible promissory notes	-	-	-	-	709,827	-	-	709,827
Warrants issued with promissory note	-	-	-	-	36,104	-	-	36,104
Beneficial conversion feature on promissory notes	-	-	-	-	35,396	-	-	35,396
Foreign currency translation adjustment	-	-	-	-	-	-	935	935
Balances as of March 31, 2018	-	$ -	141,050,550	$ 141,051	$ 96,794,440	$ (110,828,039)	$ (42,848)	$ (13,935,396)
Net loss	-	-	-	-	-	(2,888,259)	-	(2,888,259)
Warrant exercises	-	-	227,273	227	24,773	-	-	25,000
Cashless warrant exercises	-	-	4,606,675	4,607	(4,607)	-	-	-
Shares issued for services	-	-	71,532	71	27,429	-	-	27,500
Warrants issued for services	-	-	-	-	737,457	-	-	737,457
Conversion of promissory notes	-	-	5,896,727	5,897	642,743	-	-	648,640
Stock-based compensation	-	-	-	-	836,796	-	-	836,796
Foreign currency translation adjustment	-	-	-	-	-	-	(11,904)	(11,904)
Balances as of June 30, 2018	-	$ -	151,852,757	$ 151,853	$ 99,059,031	$ (113,716,298)	$ (54,752)	$ (14,560,166)
Balances as of January 1, 2019	-	-	155,665,138	155,665	101,153,882	(116,602,778)	(62,868)	(15,356,099)
Net loss	-	-	-	-	-	(2,197,317)	-	(2,197,317)
Cashless warrant exercises	-	-	704,108	704	(704)	-	-	-
Proceeds from warrant exercise	-	-	620,000	620	52,580	-	-	53,200
Other warrant exercise	-	-	3,333,334	3,334	263,333	-	-	266,667
Reclassification of warrant liability to equity	-	-	-	-	262,339	1,279,661	-	1,542,000
Foreign currency translation adjustment	-	-	-	-	-	-	(2,398)	(2,398)
Balances as of March 31, 2019	-	$ -	160,322,580	$ 160,323	$ 101,731,430	$ (117,520,434)	$ (65,266)	$ (15,693,947)
Net loss	-	-	-	-	-	(2,734,431)	-	(2,734,431)
Cashless warrant exercises	-	-	2,997,375	2,997	13,003	-	-	16,000
Proceeds from warrant exercise	-	-	17,051,769	17,052	1,333,005	-	-	1,350,057
Other warrant exercise	-	-	5,804,167	5,804	451,697	-	-	457,501
Conversion of line of credit, related parties to equity			2,475,000	2,475	177,525			180,000
Stock-based compensation	-	-	-	-	31,758	-	-	31,758
Warrants issued for consulting services	-	-	-	-	36,067	-	-	36,067
Foreign currency translation adjustment	-	-	-	-	-	-	1,489	1,489
Balances as of June 30, 2019	-	$ -	188,650,891	$ 188,651	$ 103,774,485	$ (120,254,865)	$ (63,777)	$ (16,355,506)

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

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

	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (4,931,748)	$ (8,744,914)
Adjustments to reconcile loss from operations		
to net cash used by operating activities		
Depreciation	17,812	11,024
Change in allowance for doubtful accounts	25,248	(61,344)
Stock-based compensation	31,758	836,796
Warrants issued for consulting services	36,067	737,457
Waived proceeds from warrant exercise	16,000	-
Loss (gain) on warrant valuation adjustment	(227,669)	1,812,162
Amortization of operating lease	(3,471)	-
Amortization of debt issuance costs	-	2,683,936
Amortization of debt discount	-	75,484
Stock issued for consulting services	-	106,500
Warrants issued for consulting services	36,067	737,457
Loss on sale of fixed assets	-	3,170
Accrued interest	936,658	168,787
Interest payable, related parties	332,671	156,746
Changes in operating assets and liabilities		
Accounts receivable - trade	34,485	69,534
Inventory	(66,112)	15,216
Prepaid expenses	(126,505)	(54,528)
Contract assets	-	(40,000)
Due from related parties	1,228	-
Other assets	(7,070)	(3,872)
Accounts payable	(135,916)	(425,489)
Accrued expenses	106,178	91,459
Accrued employee compensation	525,487	194,194
Operating leases	44,623	-
Contract liabilties	3,642	769,480
NET CASH USED BY OPERATING ACTIVITIES	(3,386,634)	(1,598,202)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(25,839)	(13,612)
NET CASH USED BY INVESTING ACTIVITIES	(25,839)	(13,612)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from short term note	1,215,000	85,000
Proceeds from warrant exercise	1,403,257	38,528
Advances from related parties	585,022	156,000
Proceeds from convertible promissory notes, net	-	1,159,785
Proceeds from line of credit, related party	-	280,500
Proceeds from note payable, product	-	96,708
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	3,203,279	1,563,313
EFFECT OF EXCHANGE RATES ON CASH	(909)	(10,969)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(210,103)	(59,470)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	364,549	730,184
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 154,446	$ 670,714
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Conversion of short term notes payable	$ 724,168	$ -
Conversion of line of credit, related party to equity	$ 180,000	$ -
Reclassification of warrant liability to equity	$ 262,339	$ -
Advances from related and unrelated parties converted to Convertible promissory note	$ -	$ 310,000
Accounts payable converted to convertible promissory notes	$ -	$ 120,000

Beneficial conversion feature on convertible debt	$ -	$ 745,223
Warrants issued with debt	$ -	$ 844,562

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

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 2019, the Company has been marketing the dermaPACE System for placement 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 ("U.S. 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 U.S. GAAP for complete financial statements. The financial information as of June 30, 2019 and for the three and six months ended June 30, 2019 and 2018 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2019.

The condensed consolidated balance sheet at December 31, 2018 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 April 1, 2019 (the "2018 Annual Report").

2. Going Concern

The Company does not currently generate significant recurring revenue and will require additional capital during 2019. As of June 30, 2019, the Company had an accumulated deficit of $120,254,865 and cash and cash equivalents of $154,446. For the six months ended June 30, 2019 and 2018, the net cash used by operating activities was $3,386,634 and $1,598,202, respectively. The Company incurred a net loss of $4,931,748 for the six months ended June 30, 2019 and a net loss of $8,744,914 for the six months ended June 30, 2018. The operating losses and the events of default on the Company's short term notes payable (see Note 7), the Company's convertible promissory notes and the notes payable, related parties (see Note 8) 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.

2. Going Concern (continued)

The continuation of the Company's business is dependent upon raising additional capital 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, 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

The significant accounting policies followed by the Company are summarized below and should be read in conjunction with the 2018 Annual Report:

Principles of consolidation - The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Estimates – These condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. Because a precise determination of assets and liabilities, and correspondingly revenues and expenses, depend on future events, the preparation of condensed consolidated financial statements for any period necessarily involves the use of estimates and assumptions. Actual amounts may differ from these estimates. These condensed consolidated financial statements have, in management's opinion, been properly prepared within reasonable limits of materiality and within the framework of the accounting policies summarized herein. Significant estimates include the recording of allowances for doubtful accounts, estimate of the net realizable value of inventory, estimated reserves for inventory, valuation of derivatives, the determination of the valuation allowances for deferred taxes, estimated fair value of stock-based compensation, and estimated fair value of warrants.

Reclassifications – Certain accounts in the prior period consolidated financial statements have been reclassified for comparison purposes to conform to the presentation of the current period consolidated financial statements. These reclassifications had no effect on the previously reported net loss.

Inventory - Inventory consists of finished medical equipment and parts and is stated at the lower of cost, which is valued using the first in, first out ("FIFO") method, or net realizable value less allowance for selling and distribution expenses. The Company analyzes its inventory levels and writes down inventory that has, or is expected to, become obsolete. As of June 30, 2019, inventory consists of goods of $357,332 and parts of $193,655, net of reserve of $127,055 for a total inventory of $423,932.

3. Summary of Significant Accounting Policies (continued)

Recently Issued or Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (Topic 842).* Subsequent to the issuance of Topic 842, the FASB clarified the guidance through several ASUs; hereinafter the collection of lease guidance is referred to as "ASC 842". The Company, using the modified retrospective approach with a cumulative-effect adjustment, recognized a right to use ("ROU") asset at the beginning of the period of adoption (January 1, 2019). Therefore, the Company recognized and measured operating leases on the condensed consolidated balance sheet without revising comparative period information or disclosure. The Company elected the package of practical expedients permitted under the transition guidance within the standard, which eliminates the reassessment of past leases, classification and initial direct costs and treats short term leases of less than a year outside of a ROU asset. The Company has no financing leases. The adoption did not materially impact the Company's Condensed Consolidated Statements of Operations or Cash Flows. Refer to Note 11, Commitments and Contingencies, for additional disclosures required by ASC 842. The Company determines if an arrangement is a lease at inception. For leases where the Company is the lessee, ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date (except we used the practical expedients and recorded the outstanding operating lease at January 1, 2019) based on the present value of lease payments over the lease term. As the Company's lease did not provide an implicit interest rate, the Company used the equivalent borrowing rate for a secured financing with the term of that equal to the remaining life of the lease at inception. The lease terms used to calculate the ROU asset and related lease liability did not include options to extend or termination of the lease; there are none and there is no reasonable certainty that the Company would extend the lease at expiration. Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense; there were no finance leases at this time which would be recognized as depreciation expense and interest expense. The Company has lease agreements which require payments for lease and non-lease components and has elected to account for these as a separate lease components. Non-leasing components are not included in the ROU asset.

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 adoption of ASU 2017-09 did not have a material impact on the Company's financial condition or results of operations.

3. Summary of Significant Accounting Policies (continued)

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. The Company has elected to apply ASU 2017-11 using a modified-retrospective approach by means of a cumulative-effect adjustment to its financial statements as of the beginning of the first fiscal year for which the account standard applies (or January 1, 2019), as allowed under ASU 2017-11. Since the adoption of ASU 2017-11 would have classified the warrants effected as equity at inception, the cumulative-effect adjustment should (i) record the issuance date value of the warrants as if they had been equity classified at the issuance date, (ii) reverse the effects of changes in the fair value of the warrants that had been recorded in the statement of comprehensive loss of each period, and (iii) eliminate the derivative liabilities form the balance sheet. Upon adoption, the Company (i) recorded an increase of $262,339 to additional paid-in capital, (ii) recorded an increase to retained earnings of $1,278,661and (iii) decreased the warrant liability by $1,542,000.

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 adoption of ASU 2018-07 had no impact on the Company's condensed consolidated 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 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 condensed consolidated financial statements.

4. Accrued expenses

Accrued expenses consist of the following:

	June 30, 2019	December 31, 2018
Accrued board of directors' fees	$ 300,000	$ 200,000
Accrued executive severance	145,000	136,000
Accrued outside services	124,078	115,118
Accrued inventory	116,502	
Accrued travel	60,000	58,993
Accrued legal fees	35,000	-
Accrued clinical study expenses	13,650	13,650
Accrued related party advances	-	101,137
Deferred rent	-	44,623
Accrued computer equipment	-	8,752
Accrued other	1,228	11,007
	$ 795,458	$ 689,280

On May 13, 2019, the Company repaid in full the outstanding balance on accrued related party advances with interest of $102,918 to Shri Parikh, the President of the Company.

5. Contract liabilities

As of June 30, 2019, the Company has contract assets and liabilities from contracts with customers (see Note 12).

Contract liabilities consist of the following:

	June 30, 2019	December 31, 2018
Deposit on product	$ 62,946	$ 92,950
Service agreement	115,538	57,365
Other	3,691	28,218
Total Contract liabilities	182,175	178,533
Non-Current	(67,361)	(46,736)
Total Current	$ 114,814	$ 131,797

The timing of the Company's revenue recognition may differ from the timing of payment by its customers. A 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 contract liability balances as of June 30, 2019, the Company expects to satisfy its remaining performance obligations associated with $114,814 and $67,361 of contract liability balances within the next twelve months and following forty-eight months, respectively. Of the aggregate contract liability balances as of December 31, 2018, the Company expects to satisfy its remaining performance obligations associated with $131,797 and $46,736 of contract liability balances within the next twelve months and following forty-eight months, respectively.

6. Advances from related parties

During the six months ended June 30, 2019, the Company has received $585,022 for warrant exercises. Due to the timing of receipt of cash and issuance of the Company's common stock the funds have been recorded as advances from related parties and will be properly recorded as equity when the common stock is issued.

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 $849,500 with an annualized interest rate of 6%. On April 30, 2019, the amount of the line of credit was decreased by $180,000 through a conversion to 2,475,000 shares of common stock. The line of credit may be called for payment upon demand of the holder. As of June 30, 2019, $726,009 was outstanding under the agreement.

Interest expense on the line of credit, related parties totaled $10,043 and $5,550 for the three months ended June 30, 2019 and 2018, respectively and $22,785 and $11,100 for the six months ended June 30, 2019 and 2018, respectively.

8. Short term notes payable

During the six months ended June 30, 2019, the Company entered into short term notes payable in the total principal amount of $1,215,000 with an interest rate of 5% per annum. The total principal, accrued interest and accrued financing costs of short term notes payable was $3,079,767 as of June 30, 2019 and are due and payable six months from the date of issuance of the respective notes.

began accruing interest at the default interest rate of 10%. On January 2, 2019, the Company defaulted on the short term notes payable issued on July 2, 2018 and began accruing interest at the default interest rate of 10%. On January 30, 2019, the Company defaulted on the short term notes payable issued on July 30, 2018 and began accruing interest at the default interest rate of 10%. In May 2019, the Company defaulted on the short term notes payable issued during November 2018 and began accruing interest at the default rate of 10%. On June 30, 2019, the Company defaulted on the short term notes payable issued on December 31, 2018 and will begin accruing interest at the default interest rate of 10% in July 2019.

On April 17, 2019, the Company offered an incentive to Class L and Class N Warrant holders in return for their funding the operations of the Company prior to an effective Registration Statement with the SEC for the Class L and Class N Warrant Agreements and certain Series A Warrants. The Company approved the issuance of a 10% bonus number of shares of the Company's common stock to be calculated by multiplying the number of shares being issued upon the Class L Warrant, Class N Warrant and Series A Warrant exercise by 10% at a cost basis equal to the exercise price and recorded interest expense in the amount of $629,963.

Interest expense on the short term notes payable totaled $675,537 and $41 for the three months ended June 30, 2019 and 2018, respectively and $705,772 and $41 for the six months ended June 30, 2019 and 2018, respectively.

9. Convertible promissory notes

The 10% Convertible Promissory Notes have a six month term from the subscription date and the note holders can convert the 10% Convertible Promissory Notes at any time during the term to the number of shares of Company common stock, $0.001 par value (the "Common Stock"), equal to the amount obtained by dividing (i) the amount of the unpaid principal and interest on the note by (ii) $0.11. The 10% Convertible Promissory Notes include a warrant agreement (the "Class N Warrant") 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 23, 2019, the Company amended the expiration date of the Class N Warrants from March 17, 2019 to May 1, 2019, effective as of January 23, 2019. On March 1, 2019, the Company amended the expiration date of the Class N Warrants from March 17, 2019 to June 28, 2019 to be effective on March 1, 2019. On May 31, 2019, the Company amended the expiration date of the Class N warrants from June 28, 2019 to September 3, 2019.

As of August 2, 2018, the Company defaulted on all of the 10% Convertible Promissory Notes issued and began accruing interest at the default interest rate of 18%.

Interest expense on the 10% Convertible Promissory Note totaled $104,051 and $1,710,280 for the three months ended June 30, 2019 and 2018, respectively, and $208,101 and $3,259,215 for the six months ended June 30, 2019 and 2018, respectively.

10. 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 was 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.

The Company is a party to 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, September 30, 2018, December 31, 2018, March 31, 2019 and June 30, 2019 (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 $5,372,743 at June 30, 2019 and December 31, 2018.

Accrued interest, related parties currently payable totaled $1,504,453 at June 30, 2019 and $1,171,782 at December 31, 2018. Interest expense on notes payable, related parties totaled $112,984 and $194,246 for the three months ended June 30, 2019 and 2018, respectively and $332,671 and $383,457 for the six months ended June 30, 2019 and 2018, respectively.

11. Equity transactions

Warrant Exercise

During the six months ended June 30, 2019, the Company issued 17,671,769 shares of Common Stock upon the exercise of 17,671,769 Class L Warrants, Class O Warrants and Series A Warrants to purchase shares of stock under the terms of the respective warrant agreements.

Cashless Warrant Exercise

During the six months ended June 30, 2019, the Company issued 3,501,483 shares of Common Stock upon the cashless exercise of 6,755,522 Class N Warrants, Class L Warrants and Series A Warrants to purchase shares of stock under the terms of the respective warrant agreements.

During the six months ended June 30, 2019, the Company issued 200,000 shares of Common Stock on a cashless basis upon the exercise of 200,000 Class L Warrants to purchase shares of stock under the terms of the respective warrant agreements. The Common Stock was issued on a cashless basis as a result of email breach in March 2019. The warrant holder sent the funds to an incorrect bank account as a result of the email breach and the Company elected to waive the requirement to cash exercise and allowed the warrant holder to net exercise.

Other Warrant Exercise

During the six months ended June 30, 2019, the Company issued 9,137,501 shares of Common Stock exercise of 9,125,001 Class L Warrants and Series A Warrants, under the terms of the respective warrant agreements. The other warrant exercise constituted the conversion of short term note payable in the principal amount of $724,168 with the receipt of notices of Class L and Series A warrant exercises all pursuant to the terms of the short term note payable.

12. Warrants

A summary of the warrant activity during the six months ended June 30, 2019, is presented as follows:

Warrant class	Outstanding as of December 31, 2018	Issued	Exercised	Expired	Outstanding as of June 30, 2019
Class K Warrants	7,200,000	-	-	-	7,200,000
Class L Warrants	57,258,339	-	(57,258,339)	-	-
Class N Warrants	30,451,815	-	(6,237,499)	-	24,214,316
Class O Warrants	7,929,091	-	(140,000)	-	7,789,091
Class P Warrants	-	365,000	-	-	365,000
Series A Warrants	1,155,682	-	(1,155,682)	-	-
	103,994,927	365,000	(64,791,520)	-	39,568,407

12. Warrants (continued)

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

	Exercise price per share	Expiration date
Class K Warrants	$ 0.08	June 2025
Class K Warrants	$ 0.11	August 2027
Class N Warrants	$ 0.11	September 2019
Class O Warrants	$ 0.11	December 2019
Class P Warrants	$ 0.20	June 2024

On January 23, 2019, the Company extended the expiration date to May 1, 2019 for Series A Warrants, Class L Warrants and Class N Warrants. On March 1, 2019, the Company extended the expiration date to June 28, 2019 for Class N Warrants and Class O Warrants. On May 31, 2019, the Company amended the expiration date of the Class N warrants from June 28, 2019 to September 3, 2019 to be effective on May 31, 2019. No consideration was given for the warrant extensions.

The Company has 28,325,002 Class L Warrants and 464,226 Series A Warrants that have been exercised but the common stock has not yet been issued. The cash for these issuable shares was previously received and recorded in Advances from related parties and Short term notes payable.

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.

On June 11, 2019, the Company issued Class P Warrant Agreements to vendors to purchase 265,000 shares of common stock at an exercise price of $0.20 per share. Each Class P Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class P Warrants at the grant date was $36,067 and was recorded as selling and marketing expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on June 11, 2024.

On June 24, 2019, the Company issued Class P Warrant Agreement to a vendor to purchase up to 100,000 shares of common stock at an exercise price of $0.20 per share. Each Class P Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class P Warrant will be recorded as selling and marketing expense and an increase to additional paid-in capital as the warrants are earned per the milestones. The warrants have not yet vested based on milestones and expire on June 24, 2024.

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.

12. Warrants (continued)

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.

A summary of the changes in the warrant liability during the six months ended June 30, 2019, is presented as follows:

	Class K Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2018	$ 1,542,000	$ 227,669	$ 1,769,669
Change in fair value	-	(32,359)	(32,359)
Expired	-	(195,310)	(195,310)
Reclassification due to Adoption of ASU 2017-11 (see Note 3)	(1,542,000)	-	(1,542,000)
Warrant liability as of June 30, 2019	$ -	$ -	$ -

13. Commitments and contingencies

Operating Leases

The Company is a party to certain operating leases. In August 2016, the Company entered into a lease agreement for 7,500 square feet of office space for office, research and development, quality control, production and warehouse space which expires on December 31, 2021. On February 1, 2018, the Company entered into an amendment to the lease agreement for an additional 380 square feet of office space for storage which expires on December 31, 2021. On January 2, 2019, the Company entered into a second amendment to the lease agreement for an additional 2,297 square feet of office space for office space which expires on December 31, 2021. Under the terms of the lease, the Company pays monthly rent of $14,651, subject to a 3% adjustment on an annual basis.

13. Commitments and contingencies (continued)

Right of use assets and Lease liability – right of use consist of the following:

	June 30, 2019
Right of use assets	$ 398,698

	June 30, 2019
Lease liability - right of use	
Current portion	$ 167,437
Long term portion	272,413
	$ 439,850

Cash paid for amounts included in the measurement of lease liabilities for the six months ended June 30, 2019 was $44,623 and was included in Net cash used in operating activities in it condensed consolidated statement of cash flows. Upon adoption of ASC 842 on January 1, 2019, the Company increased non-cash balances of right of use assets and lease liability – right of use by $476,029 and $520,652, respectively.

As of June 30, 2019, the maturities of the Company's lease liability – right of use which have initial or remaining lease terms in excess of one year consist of the following:

Year ending December 31,	Amount
2019 (remainder)	$ 94,213
2020	191,713
2021	197,462
Total lease payments	483,388
Less: Present value adjustment	(43,538)
Lease liability - right of use	$ 439,850

Year ending December 31,	Amount
2019 (remainder)	$ 94,213
2020	191,713
2021	197,462
Total	$ 483,388

Rent expense for the three months ended June 30, 2019 and 2018 was $54,698 and $36,138, respectively, and for the six months ended June 30, 2018 and 2017 was $107,536 and $72,020, respectively.

As of June 30, 2019, the Company had no leases that were classified as a financing lease. As of June 30, 2019, the Company did not have additional operating or financing leases that have yet commenced.

13. Commitments and contingencies (continued)

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.

14. Revenue

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 six months ended June 30, 2019 and 2018:

	Three months ended June 30, 2019			Three months ended June 30, 2018		
	United States	International	Total	United States	International	Total
Product	$ 120,488	$ 100,179	$ 220,667	$ 18,893	$ 224,572	$ 243,465
License fees	6,250	60,558	66,808	6,250	197,507	203,757
Other Revenue	-	29,501	29,501	-	5,988	5,988
	$ 126,738	$ 190,238	$ 316,976	$ 25,143	$ 428,067	$ 453,210

	Six months ended June 30, 2019			Six months ended June 30, 2018		
	United States	International	Total	United States	International	Total
Product	$ 138,167	$ 147,065	$ 285,232	$ 135,340	$ 346,693	$ 482,033
License fees	12,500	160,558	173,058	12,500	275,373	287,873
Other Revenue	-	36,649	36,649	-	27,576	27,576
	$ 150,667	$ 344,272	$ 494,939	$ 147,840	$ 649,642	$ 797,482

On June 4, 2019, we entered into an agreement with Johnfk Medical Inc. (“FKS”) and Holistic Wellness Alliance Pte. Ltd. (“HWA”) pursuant to which we and FKS terminated the joint venture agreement, dated as of September 21, 2018, that established HWA as a joint venture between us and FKS. Pursuant to such agreement, FKS will pay us the outstanding amount of $63,275 for equipment delivered to FKS and a penalty fee of $50,000 for early termination of the joint venture agreement. We received a partial payment of $10,000 for the early termination of the joint venture agreement on July 18, 2019.

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. Three distributors accounted for 30%, 28% and 15% of revenues for the six months ended June 30, 2019 and 49%, 0% and 25% of accounts receivable at June 30, 2019. Three distributors and partners accounted for 24%, 60% and 7% of accounts receivable at December 31, 2018.

15. Related party transactions

During the three and six months ended June 30, 2019 and 2018, the Company recorded $17,678 and $114,810 and $138,167 and $124,491, respectively, in revenue from an entity owned by A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. Contract liabilities includes a balance at June 30, 2019 and 2018, of $102,899 and $53,682, respectively and the Accrued expenses balance includes a balance at June 30, 2019 and 2018, of $0 and $130,478, respectively from this related party.

16. Stock-based compensation

On June 14, 2019, the Company granted to consultant an option to purchase up to 475,000 shares of the Company's common stock at an exercise price of $0.18 per share. 100,000 shares subject to the option vested upon issuance and the remaining 375,000 shares subject to the option will vest based on performance milestones. Using a "closed-form" Black-Scholes option pricing model, management has determined that the vested shares had a fair value per share of $0.15 resulting in compensation expense of $15,000. The vested compensation cost was recognized upon grant. The unvested compensation cost will be recognized as the performance milestones are completed.

On June 11, 2019, the Company granted to two new employees options to purchase an aggregate of 105,000 shares of the Company's common stock at an exercise price of $0.16 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the shares subject to the option had a fair value per share of $0.1596 resulting in compensation expense of $16,758. Compensation cost was recognized upon grant.

During the six months ended June 30, 2019, 100,000 options to purchase common stock were forfeited.

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, $31,758 and $836,796 for the three months ended June 30, 2019 and 2018, respectively, and $31,758 and $836,796 for the six months ended June 30, 2019 and 2018, respectively.

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at June 30, 2019 and December 31, 2018, respectively. The aggregate intrinsic value for all vested and exercisable options was $664,516 and $2,085,866 at June 30, 2019 and December 31, 2018, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options was 6.92 and 7.4 years as of June 30, 2019 and December 31, 2018, respectively.

17. Earnings (loss) per share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share as their inclusive would be anti-dilutive and consist of the following:

	June 30, 2019	June 30, 2018
Options	32,183,385	23,723,385
Warrants	39,568,407	108,355,714
Shares issuable	28,789,228	-
Convertible promissory notes	26,004,347	-
	126,545,367	132,079,099

18. Subsequent events

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

Warrant Exercise

Subsequent to June 30, 2019, the Company issued 1,591,667 shares of Common Stock upon the exercise of 1,591,667 Class L Warrants to purchase shares of stock under the terms of the respective warrant agreements.

Warrant Exercise – Short term notes payable

Subsequent to June 30, 2019, the Company issued 5,341,666 shares of Common Stock upon the exercise of 5,341,666 Class L Warrants converting funds from short term notes payable to purchase shares of stock under the terms of the warrant agreement.

Cashless Warrant Exercise

Subsequent to June 30, 2019, the Company issued 307,874 shares of Common Stock upon the cashless exercise of 622,909 Class N Warrants to purchase shares of stock under the terms of the warrant agreement.

Equipment Lease

Subsequent to June 30, 2019, the Company entered into the third drawdown of the Master Equipment Lease with NFS Leasing Inc. in the amount of $224,954.

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, 2018 included in our Annual Report on Form 10-K, filed with the SEC on April 1, 2019.

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 and was cleared by the U.S. Food and Drug Administration ("FDA") on December 28, 2017.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. In 2018, we 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.

Our lead product candidate for the global wound care market, dermaPACE, has received FDA clearance for commercial use to treat diabetic foot ulcers in the United States and the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. 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 orthoPACE®, OssaTron, and Evotron® devices in Europe and Asia.

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.

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 $1cm^2$ and $16cm^2$, 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.

Clinical Studies

A dosage study has been developed for launch in Poland to optimize dermaPACE system treatment dosage for producing a more rapid reduction in size of a diabetic foot ulcer ("DFU"). The focus will be on increasing the number of shock waves delivered per treatment, as a function of DFUs area. To determine the dosage necessary, three new distinctive regimens will be assessed during the study. This study started in April 2019 and is expected to be finalized late in the fourth quarter of 2019.

A post-market pilot study to evaluate the effects of high energy acoustic shock wave therapy on local skin perfusion and healing of DFUs will be conducted at two sites: one in New Jersey and one in California. The intent of this trial is to quantify the level of increased perfusion and oxygenation during and after treatment with the dermaPACE system. Enrollment and first patient treatment started in April 2019.

Financial Overview

Since our inception, we have incurred losses from operations each year. As of June 30, 2019, we had an accumulated deficit of $120,254,865. 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 "Liquidity and Capital Resources" for further information regarding our financial 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, 2018, filed with the SEC on April 1, 2019.

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, 2018, filed with the SEC on April 1, 2019, we believe that the following accounting policies relating to revenue recognition, liabilities related to warrants issued, and stock-based compensation 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.

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 June 30, 2019 and 2018

Revenues and Cost of Revenues

Revenues for the three months ended June 30, 2019 were $316,976, compared to $453,210 for the same period in 2018, a decrease of $136,234, or 30%. Revenue resulted primarily from sales in Europe of our orthoPACE devices and related applicators and sales in the United States of our dermaPACE applicators. The decrease in revenue for 2019 is primarily due to a decrease in sales of new and refurbished applicators in Asia/Pacific and the European Community and lower upfront international distribution fees, as compared to the prior year. This is partially offset by higher device sales in the United States and Asia/Pacific.

Cost of revenues for the three months ended June 30, 2019 were $185,881, compared to $166,643 for the same period in 2018. Gross profit as a percentage of revenues was 41% for the three months ended June 30, 2019, compared to 63% for the same period in 2018. The decrease in gross profit as a percentage of revenues in 2019 was primarily due to increased sale of devices that have a lower margin and cost of new and refurbished dermaPACE applicators in the United States as a result of placements.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2019 were $307,273, compared to $328,753 for the same period in 2018, a decrease of $21,480, or 7%. The decrease in research and development expenses in 2019, as compared to 2018, was due to a reclassification of employees and related costs from research and development to general and administrative in 2019. This is partially offset by an increase in contracting for temporary services and increased study expenses related to our new dosage study in Poland.

Selling and Marketing Expenses

Selling and marketing expenses for the three months ended June 30, 2019 were $407,477, compared to $158,695 for the same period in 2018, an increase of $248,782, or 157%. The increase in selling and marketing expenses in 2019, as compared to 2018, was due to an increase in hiring of trainers and salespeople and increased travel expenses for placement and training related to the commercialization of dermaPACE.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2019 were $1,426,405, as compared to $1,911,688 for the same period in 2018, a decrease of $485,283, or 25%. The decrease in general and administrative expenses in 2019, as compared to 2018, was due to a decrease in stock based compensation expense related to options issued in 2018, lease expense related to pay-off of lease agreement for devices in 2018 and lower investor relations costs. This is partially offset by an increase in salary, bonus and benefits related to new hires in 2018.

Depreciation

Depreciation for the three months ended June 30, 2019 was $9,455, compared to $6,008 for the same period in 2018, an increase of $3,447, or 57%. The increase was due to the higher depreciation related to increase in fixed assets.

Other Income (Expense)

Other income (expense) was a net expense of $714,916 for the three months ended June 30, 2019 as compared to a net expense of $766,512 for the same period in 2018, a decrease of $51,596, or 7%, in the net expense. The decrease was primarily due to decreased interest expense, beneficial conversion discount and debt discount related to the convertible promissory notes issued in the fourth quarter of 2017 and first quarter of 2018. This is partially offset by financing charge in 2019 related to short term notes and 2019 included a non-cash gain for valuation adjustment on outstanding warrants of $195,310, as compared to $1,161,520 for the same period in 2018.

Net Loss

Net loss for the three months ended June 30, 2019 was $2,734,431, or ($0.02) per basic and diluted share, compared to a net loss of $2,888,259, or ($0.02) per basic and diluted share, for the same period in 2018, a decrease in the net loss of $153,828, or 5%.

Results of Operations for the Six Months ended June 30, 2019 and 2018

Revenues and Cost of Revenues

Revenues for the six months ended June 30, 2019 were $494,939, compared to $797,482 for the same period in 2018, a decrease of $302,543, or 38%. Revenue resulted primarily from sales in Europe of our orthoPACE devices and related applicators, sales in the United States of our dermaPACE applicators and upfront distribution fee from our Southeast Asia distribution agreement with Johnfk Medical Inc. (“FKS”). The decrease in revenue for 2019 is primarily due to a decrease in sales of orthoPACE devices in Asia/Pacific and the European Community and sales of dermaPACE devices in the United States, lower sales of new and refurbished applicators and reduced upfront distribution fee, as compared to the prior year.

Cost of revenues for the six months ended June 30, 2019 were $279,734, compared to $332,109 for the same period in 2018. Gross profit as a percentage of revenues was 43% for the six months ended June 30, 2019, compared to 58% for the same period in 2018. The decrease in gross profit as a percentage of revenues in 2019 was primarily due to cost of new and refurbished dermaPACE devices and applicators in the United States as a result of placements.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2019 were $567,922, compared to $678,197 for the same period in 2018, a decrease of $110,275, or 16%. The decrease in research and development expenses in 2019, as compared to 2018, was due to a reclassification of employees and related costs from research and development to general and administrative in 2019. This is partially offset by an increase in contracting for temporary services and increased study expenses related to our new dosage study in Poland.

Selling and Marketing Expenses

Selling and marketing expenses for the six months ended June 30, 2019 were $565,559, compared to $210,654 for the same period in 2018, an increase of $354,905, or 168%. The increase in sales and marketing expenses in 2019, as compared to 2018, was due to an increase in hiring of trainers and salespeople and increased travel expenses for placement and training related to the commercialization of dermaPACE.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2019 were $2,943,860, as compared to $2,805,335 for the same period in 2018, an increase of $138,525, or 5%. The decrease in general and administrative expenses in 2019, as compared to 2018, was due to decrease in stock based compensation expense related to option issued in 2018, lease expense related to pay-off of lease agreement for devices in 2018 and lower investor relations costs. This is partially offset by an increase in salary, bonus and benefits related to new hires in 2018.

Depreciation

Depreciation for the six months ended June 30, 2019 was $17,812, compared to $11,024 for the same period in 2018, an increase of $6,788, or 62%. The increase was due to the higher depreciation related to increase in fixed assets.

Other Income (Expense)

Other income (expense) was a net expense of $1,051,800 for the six months ended June 30, 2019 as compared to a net expense of $5,501,907 for the same period in 2018, a decrease of $4,450,107, or 81%, in the net expense. The decrease was primarily due to decreased interest expense, beneficial conversion discount and debt discount related to the convertible promissory notes issued in the fourth quarter of 2017 and first quarter of 2018. In addition, the net expense in 2019 included a non-cash gain for valuation adjustment on outstanding warrants of $227,669, as compared to a non-cash loss for valuation adjustment on outstanding warrants of $1,812,162 in 2018.

Net Loss

Net loss for the six months ended June 30, 2019 was $4,931,748, or ($0.03) per basic and diluted share, compared to a net loss of $8,744,914, or ($0.06) per basic and diluted share, for the same period in 2018, a decrease in the net loss of $3,813,166, or 44%. The decrease in the net loss was primarily a result of a decrease in other income (expense), partially offset by an increase in our operating expenses as described above.

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 $4,931,748 for the six months ended June 30, 2019 and $11,631,394 for the year ended December 31, 2018. These factors along with the events of default on the notes payable to HealthTronics, Inc., the Company's convertible promissory notes and the Company's short term notes payable create substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the financial issuance date.

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

We have entered into short term notes payable with twenty-four individuals between June 26, 2018 and April 10, 2019 in the total principal amount of $2,835,525 with an interest rate of 5% 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. On December 26, 2018, the Company defaulted on the short term notes payable issued on June 26, 2018 and began accruing interest at the default interest rate of 10%. On January 2, 2019, the Company defaulted on the short term notes payable issued on July 2, 2018 and began accruing interest at the default interest rate of 10%. On January 30, 2019, the Company defaulted on the short term notes payable issued on July 30, 2018 and began accruing interest at the default interest rate of 10%. In May 2019, the Company defaulted on the short term notes payable issued during November 2018 and began accruing interest at the default rate of 10%. On June 30, 2019, the Company defaulted on the short term notes payable issued on December 31, 2018 and will begin accruing interest at the default interest rate of 10% in July 2019.

The continuation of our business is dependent upon raising additional capital to fund operations. Management expects the cash used in operations for the Company will be approximately $275,000 to $350,000 per month for the remainder of 2019 as resources are devoted to the commercialization of the dermaPACE product including hiring of new employees, expansion of our international business and continued research and development of non-medical uses of our technology. Management's plans are to obtain additional capital in 2019 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, 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. In addition, there can be no assurances that our plans to obtain additional capital will be successful on the terms or timeline we expect, or at all. A $400,000 fee we anticipated receiving in April 2019 from FKS under the terms of a June 2018 agreement has not been received to date, and on June 4, 2019, we entered into an agreement with FKS and Holistic Wellness Alliance Pte. Ltd. ("HWA") pursuant to which we and FKS terminated the joint venture agreement, dated as of September 21, 2018, that established HWA as a joint venture between us and FKS. Pursuant to such agreement, FKS will pay us the outstanding amount of $63,275 for equipment delivered to FKS and a penalty fee of $50,000 for early termination of the joint venture agreement. We received a partial payment of $10,000 for the early termination of the joint venture agreement on July 18, 2019. 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 required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. 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.

In addition, we may have potential liability for certain sales, offers or issuances of equity securities of the Company in possible violation of federal securities laws. Pursuant to a Registration Statement on Form S-1 (Registration No. 333-208676), declared effective on February 16, 2016 (the "2016 Registration Statement"), the Company sought to register: a primary offering of up to $4,000,000 units, the Common Stock included as part of the units, the warrants included as part of the units, and the Common Stock issuable upon exercise of such warrants; a primary offering of up to $400,000 placement agent warrants and the Common Stock issuable upon exercise of such placement agent warrants; and a secondary offering of 23,545,144 shares of Common Stock held by certain selling stockholders named in the 2016 Registration Statement. The SEC Staff's interpretations provide that, when an issuer is registering units composed of common stock, common stock purchase warrants, and the common stock underlying the warrants, the registration fee is based on the offer price of the units and the exercise price of the warrants. The registration fee paid did include the fee based on the offer price of the units, allocated to the unit line item in the fee table. Although the fee table in the 2016 Registration Statement included a line item for the Common Stock underlying the warrants, the Company did not include in that line item the fee payable based on the exercise price of $0.08 per share for such warrants, which amount should have been allocated to such line item based on the SEC Staff's interpretations. As a result, a portion of the securities intended to be registered by the 2016 Registration Statement was not registered. In addition, in a post-effective amendment to the 2016 Registration Statement filed on September 23, 2016, too many placement agent warrants were inadvertently deregistered. The post-effective amendment stated that the Company had issued $180,100, based on 2,251,250 Class L warrants issued with a $0.08 exercise price of warrants to the placement agent and therefore deregistered $219,900, based on 2,748,750 Class L warrants issued with a $0.08 exercise price of placement agent warrants from the $400,000, based on 5,000,000 Class L warrants issued with a $0.08 exercise price total offering amount included in the Registration Statement. The actual warrants issued to the placement agent totaled $240,133.36, based on 3,001,667 Class L warrants issued with a $0.08 exercise price, and only $159,867, based on 1,998,338 Class L warrants issued with a $0.08 exercise price should have been deregistered in such post-effective amendment. To the extent that we have not registered or failed to maintain an effective registration statement with respect to any of the transactions in securities described above and with respect to our ongoing offering of shares of Common Stock underlying the warrants, and a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible holders of our securities that participated in these offerings would have a right to rescind their transactions, and the Company may have to refund any amounts paid for the securities, which could have a materially adverse effect on the Company's financial condition. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act with respect to these transactions, but they could file a claim in the future. Furthermore, the ongoing offering of and issuance of shares of Common Stock underlying certain of our warrants from the 2016 Registration Statement may have been, and may continue to be, in violation of Section 5 of the Securities Act and the rules and regulations under the Securities Act, because we did not update the prospectus in the 2016 Registration Statement for a period of time after the 2016 Registration Statement was declared effective and because our reliance on Rule 457(p) under the Securities Act in an amendment to our Registration Statement on Form S-1 (Registration No. 333-213774) filed on September 23, 2016 effected a deregistration of the securities registered under the 2016 Registration Statement. Eligible securityholders have not filed a claim against the Company alleging a violation of Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of Section 5 of the Securities Act did in fact occur or is occurring, eligible securityholders would have a right to rescind their transactions, and the Company may have to refund any amounts paid the securities, which could have a materially adverse effect on the Company's financial condition.

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

Cash and cash equivalents decreased by $210,103 for the six months ended June 30, 2019 and decreased by $59,470 for the six months ended June 30, 2018. For the six months ended June 30, 2019 and 2018, net cash used by operating activities was $3,386,634 and $1,598,202, respectively, primarily consisting of compensation costs, dermaPACE commercialization activities and general corporate operations. The increase of $1,788,432 in the use of cash for operating activities for the six months ended June 30, 2019, as compared to the same period for 2018, was primarily due to the increased accrued operating and payroll related expenses and increased inventory and prepaid expenses in 2019. Net cash used by investing activities for the six months ended June 30, 2019 and 2018, consisted of purchase of property and equipment of $25,839 and $13,612, respectively. Net cash provided by financing activities for the six months ended June 30, 2019 was $3,219,279, which consisted of $1,403,257 from the exercise of warrants, $1,231,000 from the issuance of short term notes payable and $585,022 from an advance from related parties. Net cash provided by financing activities for the six months ended June 30, 2018 was $1,563,313, which consisted of $144,000 net from advances from related parties, $38,528 from exercise of warrants, $1,159,785 from the issuance of convertible promissory notes, $85,000 from issuance of short term notes payable and $136,000 net from increase in line of credit, related party.

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, 2018, as filed with the SEC on April 1, 2019.

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 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 June 30, 2019. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not operating effectively as of June 30, 2019. Our disclosure controls and procedures were not effective because of the “material weakness” described below under “Management’s Annual Report on Internal Control over Financial Reporting.”

Management’s Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. The Company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Management, with the participation of the Chief Executive Officer (principal executive officer) and the Chief Financial Officer (principal financial and accounting officer), evaluated the effectiveness of the Company’s internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework (2013).

A “material weakness” is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis by the company’s internal controls. As a result of its review, management concluded that we had three material weaknesses in our internal control over financial reporting process. The first material weakness is 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 is due to the lack of internal resources to analyze and properly apply generally accepted accounting principles to accounting for equity components of service agreements with select vendors. The third material weakness relates to our information technology infrastructure. This material weakness is due to cybersecurity breaches from email spoofing. As a result, management concluded that our internal control over reporting was not effective as of June 30, 2019.

Management's Plan to Remediate Material Weaknesses

Management has developed a 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 remediation plan consists of, among other things, engaging a third party financial reporting consulting firm to assist the Company in its financial reporting compliance and redesigning the procedures to enhance the 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 has engaged a third party consultant, who is a technical accounting professional, to assist us in the interpretation and application of new and complex accounting guidance. Management will continue to review and make necessary changes to the overall design of our internal control environment. These measures are intended both to address the identified material weaknesses and to enhance our overall internal control environment.

Management will develop a remediation plan to address the material weakness related to its information technology infrastructure. The remediation plan will include, but not be limited to cybersecurity training for all employees and redesign of procedures that cyber security breaches may impact.

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 14—“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
4.1	Letter to Class N Warrant Holders, dated June 5, 2019 (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on June 7, 2019).
4.2	Letter to Class O Warrant Holders, dated June 5, 2019 (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on June 7, 2019).
10.1	Deed of Termination of Joint Venture Agreement, dated June 4, 2019, by and among the Company, Johnfk Medical Inc. and Holistic Wellness Alliance Pte. Ltd. (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on June 17, 2019).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1**	Section 1350 Certification of the Principal Executive Officer.
32.2**	Section 1350 Certification of the Chief Financial Officer.
101.INS*†	XBRL Instance.
101.SCH*†	XBRL Taxonomy Extension Schema.
101.CAL*†	XBRL Taxonomy Extension Calculation.
101.DEF*†	XBRL Taxonomy Extension Definition.
101.LAB*†	XBRL Taxonomy Extension Labels.
101.PRE*†	XBRL Taxonomy Extension Presentation.

* Filed herewith.
** 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: August 14, 2019

By: /s/ *Kevin A. Richardson, II*
Name: Kevin A. Richardson, II
Title: 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	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	August 14, 2019
By: /s/ *Lisa E. Sundstrom* Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	August 14, 2019