SANUWAVE Health, Inc.
Form S-1/A
December 06, 2018

As filed with the Securities and Exchange Commission on December 6, 2018
Registration No. 333-213774

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

AMENDMENT NO. 8 TO
FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

SANUWAVE Health, Inc.
(Exact name of registrant as specified in its charter)

Nevada (State or other Jurisdiction of Incorporation or Organization)	3841 (Primary Standard Industrial Classification Code Number)	20-1176000 (I.R.S. Employer Identification No.)

3360 Martin Farm Road, Suite 100 Suwanee, Georgia 30024
(770) 419-7525
(Address, including zip code, and telephone number, including area code, of registrants principal executive offices)

Kevin A. Richardson, II
Chief Executive Officer
SANUWAVE Health, Inc.
3360 Martin Farm Road, Suite 100
Suwanee, Georgia 30024
(770) 419-7525
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Murray Indick, Esq.
John M. Rafferty, Esq.
Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105
(415) 268-7000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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.

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 137(a)(2)(B) of the Securities Act.

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered (1)	Amount to be registered	Proposed maximum offering price per share(4)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, $0.001 par value	2,574,626	$0.2375	$611,474	$74.11
Common Stock, $0.001 par value (2)	55,540,587	$0.2375	$13,190,889	$1,598.74
Common Stock, $0.001 par value (3)	3,012,934	$0.2375	$715,572	$86.73
Total	61,128,147		$14,517,935	$1,759.57

(1) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock, $0.001 par value ("Common Stock"), as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(2) Represents shares of Common Stock which may be issued upon the exercise of outstanding Class L warrants and Series A warrants.

(3) Represents shares of Common Stock which may be issued upon the exercise of outstanding Class L and Series A warrants, which warrants issued to the placement agents in connection with the private placements described herein.

(4) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, based on the per share average of the high and low reported prices for the common stock on the Over the Counter Bulletin Board as of December 3, 2018.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. Neither, we nor the selling stockholders, may sell the securities described herein until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell the securities and it is not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus, Subject to Completion, Dated December 6, 2018.

61,128,147 Shares
(Common Stock, $0.001 par value)

This prospectus relates to up to 61,128,147 shares of our common stock, par value $0.001 (“Common Stock"), being offered by the selling stockholders listed in this prospectus. The shares consist of (i) 2,574,626 outstanding shares of Common Stock held by such selling stockholders, (ii) 55,540,587 shares of Common Stock issuable upon the exercise of certain warrants held by such selling stockholders, and (iii) 3,012,934 shares of Common Stock issuable upon exercise of certain warrants issued to the placement agents for the private placements described herein. The shares offered by this 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 herein under “Plan of Distribution.”

We will receive none of the proceeds from the sale of the shares by the selling stockholders. We may receive proceeds upon the exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol SNWV.QB. The high and low bid prices for shares of our Common Stock on December 3, 2018; were $0.25 and $0.225 per share, respectively, based upon bids that represent prices quoted by broker-dealers on the OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 7 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is_____, 2018

You may rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities in any circumstances in which such offer or solicitation is unlawful. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our securities. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled ‘‘Prospectus Summary,’’ ‘‘Risk Factors,’’ ‘‘Management’s Discussion and Analysis of Financial Condition and Results of Operations’’ and ‘‘Business,’’ contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933. Statements in this prospectus that are not historical facts are hereby identified as ‘‘forward-looking statements’’ for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended (the “Securities Act”). Forward-looking statements convey our current expectations or forecasts of future events. All statements in this prospectus, 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, business strategies, projected costs, products, competitive positions, management’s plans and objectives for future operations, and industry trends. These forward-looking statements are based on management’s estimates, projections and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” and “co negative of these terms, or other comparable terminology. These forward-looking statements include, among other things, statements about:

market acceptance of and demand for dermaPACE and our product candidates;

regulatory actions that could adversely affect the price of or demand for our approved products;

our intellectual property portfolio;

our marketing and manufacturing capacity and strategy, including our efforts to expand the marketing and sales of our products in Asia and Latin America through joint ventures and other contractual arrangements;

estimates regarding our capital requirements, anticipated timing of the need for additional funds, and our expectations regarding future capital-raising transactions, including potential tender offers for certain of our outstanding series of warrants;

product liability claims;

economic conditions that could adversely affect the level of demand for our products;

timing of clinical studies and eventual FDA approval of our products;

financial markets; and

the competitive environment.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in the section titled ‘‘Risk Factors.’’ In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not

occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should read this prospectus and the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission (the “SEC”) after the date of this prospectus.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary may not contain all of the information that you should consider before investing in our Common Stock. You should carefully read the entire prospectus, including Risk Factors and the consolidated financial statements, before making an investment decision.

Unless the context requires otherwise, the words SANUWAVE, we, Company, us, and our in this prospectus refer to SANUWAVE Health, Inc. and our subsidiaries.

Our Company

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

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

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 Premarket Approvals ("PMAs") approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe and Asia.

Product Overview; Strategy

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

For more information about the Company, see the section entitled “Business” in this prospectus.

Recent Developments

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.

On September 27, 2017, we entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), effective as of September 25, 2017, for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed will pay the Company an initial upfront distribution fee, with monthly upfront distribution fees payable thereafter over the following eighteen months. Profits from the joint venture are distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial upfront distribution fee was received on October 6, 2017. Monthly upfront distribution fee payments have been received through May 2018. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company received a response letter stating that the Company was in default of the agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. The Company is currently in discussions with a new partner to take over this agreement for the marketing and distribution of its products in Brazil.

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

On June 26, 2018, the Company entered into an Agreement with Johnfk Medical Inc. ("FKS"), effective as of June 14, 2018, pursuant to which the Company and FKS committed to enter into a joint venture for the manufacture, sale and distribution of the Company's dermaPACE and orthoPACE devices. Under the Agreement, FKS paid the Company a fee of $500,000 for initial distribution rights in Taiwan on June 22, 2018, with an additional fee of $500,000 for initial distribution rights in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam (the "SEA Region") to be paid in the fourth quarter of 2018. On September 21, 2018, the Company entered into a joint venture agreement (the "JV Agreement") with FKS setting forth the terms of the operation, management and control of a joint venture entity initially with the name of Holistic Health Institute Pte. Ltd., a private limited company to be incorporated in the Republic of Singapore, but with such company name subject to confirmation by Singapore Government. On November 9, 2018, the joint venture entity was incorporated in the Republic of Singapore with the name of Holistic Wellness Alliance Pte. Ltd. ("HWA"). HWA was formed as a joint venture of the Company and FKS for the manufacture, sale and distribution of the Company's dermaPACE® and orthoPACE® devices. Under the JV Agreement, the Company and FKS each hold shares constituting fifty percent of the issued share capital of HWA. The Company provides to HWA FDA and CE approved products for an agreed cost, access to treatment protocols, training, marketing and sales materials and management expertise, and FKS provides to HWA capital, human capital

and sales resources in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam, certain reports and identification of new key opinion leaders as well as clinical trial and poster access availability. The JV Agreement also established the corporate governance of HWA, including a five-person board of directors consisting of two directors designated by the Company, two directors designated by FKS, and a third director appointed jointly by the parties. Initially, net profits under the JV Agreement shall be used to repay FKS for (i) the payment of $500,000 on June 22, 2018 to the Company for initial distribution rights in Taiwan and (ii) the cash advance to HWA per the terms of the JV Agreement. The JV Agreement includes other customary terms, including regarding the transfer of shares, indemnification and confidentiality.

After the SEC declares the registration statement to which this prospectus relates (the "Registration Statement") effective, we anticipate launching a tender offer for the Class L warrants. The Registration Statement relates to the offering by the selling stockholders of up to 61,128,147 shares of our Common Stock, which amount includes 54,600,005 shares of Common Stock issuable upon the exercise of certain Class L warrants issued in transactions as described under "Selling Stockholders" and 2,797,834 shares of Common Stock issuable upon exercise of certain Class L warrants issued to the placement agents for the private placements described herein. Under the terms of the Class L warrants, once the Registration Statement is declared effective by the SEC, holders of Class L warrants will be required to pay the per share exercise price due upon any exercise of such warrants on a cash basis. In order to incentivize holders of the Class L warrants to exercise such warrants, we anticipate launching a tender offer for such Class L warrants (the "Class L warrant tender offer") whereby we will offer holders of the Class L warrants the opportunity to amend and exercise their warrant at a reduced exercise price until the expiration date of such Class L warrant tender offer. We will announce the terms and conditions of the Class L warrant tender offer subsequent to the effectiveness of the Registration Statement in a Schedule TO-I to be filed with the SEC.

We cannot assure you that the Class L warrant tender offer will be announced on the terms described in this prospectus, or at all. Nothing in this prospectus should be construed as an offer to purchase any of our outstanding Class L warrants. The Class L warrant tender offer, if and to the extent it is announced, will be made only upon the terms and conditions set forth in the offer to purchase therefor, and related letter of transmittal and notice of guaranteed delivery.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. We have a limited operating history and have incurred substantial losses since inception. We expect to continue to incur losses for the foreseeable future and are unable to predict the extent of future losses or when we will become profitable, if at all. Our products are in various stages of research and development, with only the dermaPACE System having received regulatory approval in the United States. Our ability to generate revenue in the future will depend heavily on the successful development and commercialization of our product candidates. Even if we succeed in developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and sustain profitability. We may be unable to maintain and protect our intellectual property, which could have a substantial impact on our ability to generate revenue. Our products are subject to regulation by governmental authorities in the United States and in other countries. Failure to comply with such regulations or to receive the necessary approvals or clearances for our product and product candidates may have a material adverse effect on our business.

Trading Market

Our Common Stock is quoted on the OTCQB under the symbol "SNWV."

Corporate Information

We were incorporated in the State of Nevada on May 6, 2004, under the name Rub Music Enterprises, Inc. ("RME"). SANUWAVE, Inc. was incorporated in the State of Delaware on July 21, 2005. In December 2006, Rub Music Enterprises, Inc. ceased operations and became a shell corporation.

On September 25, 2009, RME and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of RME (the "Merger Sub") entered into a reverse merger agreement with SANUWAVE, Inc. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, Inc., with SANUWAVE, Inc. as the surviving entity (the "Merger") and a wholly-owned subsidiary of the Company.

In November 2009, we changed our name to SANUWAVE Health, Inc. Our principal executive offices are located at 3360 Martin Farm Road, Suite 100, Suwanee, Georgia 30024, and our telephone number is (770) 419-7525. Our website address is www.sanuwave.com. The information on our website is not a part of this prospectus.

THE OFFERING

Total Common Stock being offered by the selling stockholders	61,128,147 shares, consisting of (i) 2,574,626 outstanding shares of Common Stock held by such selling stockholders, (ii) 55,540,587 shares of Common Stock issuable upon the exercise of certain Class L and Series A warrants held by such selling stockholders, and (iii) 3,012,934 shares of Common Stock issuable upon exercise of certain Class L and Series A warrants issued to the placement agents for the private placements described herein.
Use of Proceeds	All net proceeds from the sale of the shares of Common Stock covered by this prospectus will go to the selling shareholders. We will receive none of the proceeds from the sale of the shares of Common Stock covered by this prospectus by the selling shareholders. We may receive proceeds upon the exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. See “Use of Proceeds.”
Risk Factors	See “Risk Factors” beginning on page 7 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Common Stock.
OTCQB Ticker Symbol for Common Stock	SNWV

SUMMARY FINANCIAL INFORMATION

The summary financial information set forth below is derived from our consolidated financial statements, including the notes thereto, appearing at the end of this prospectus. Our historical results are not necessarily indicative of the results that may be achieved in any future period, and results for any interim period are not necessarily indicative of the results to be expected for the full year. The summary financial information should be read together with our consolidated financial statements, including the notes thereto, appearing at the end of this prospectus, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	Nine Months Ended		Year Ended	
	September 30, 2018	September 30, 2017	December 31, 2017	December 31, 2016
Consolidated Statement of Operations Data				
Revenue	$1,393,271	$422,199	$738,527	$1,376,063
Net loss	$(9,570,056)	$(2,760,794)	$(5,537,936)	$(6,439,040)
Weighted average shares outstanding	147,550,321	138,711,527	138,838,602	107,619,869
Net loss per share - basic and diluted	$(0.06)	$(0.02)	$(0.04)	$(0.06)
Consolidated Balance Sheet Data (at end of period)				
Working deficit	$(13,530,957)	$(9,096,580)	$(9,955,113)	$(7,002,324)
Total assets	$723,604	$565,310	$1,278,810	$1,004,870
Total liabilities	$14,191,386	$9,588,573	$11,159,637	$7,916,470
Total stockholders' deficit	$(13,467,782)	$(9,023,263)	$(9,880,827)	$(6,911,600)

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus, including the consolidated financial statements and the related notes appearing at the end of this prospectus, before purchasing our Common Stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In any such event, the market price of our Common Stock could decline and you could lose all or part of your investment.

Risks Related to our Business

Our recurring losses from operations and dependency upon future issuances of equity or other financing to fund ongoing operations have raised substantial doubts as to our ability to continue as a going concern. We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so, and/or the terms of any financings may not be advantageous to us.

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources for the commercialization of the dermaPACE and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $9,570,056 for the nine months ended September 30, 2018 and a net loss of $5,537,936 for the year ended December 31, 2017. These operating losses and the events of default on the notes payable, to HealthTronics, Inc. and the Company's convertible promissory notes create uncertainty about our ability to continue as a going concern.

At September 30, 2018, we had cash and cash equivalents totaling $72,311 and negative working capital of $13,530,957. For the nine months ended September 30, 2018 and 2017, our net cash used by operating activities was $2,271,566 and $944,831, respectively. Management expects the cash used in operations for the Company will be approximately $175,000 to $250,000 per month for the remainder of 2018 and into 2019 as resources are devoted to the expansion of our international business, preparations for commercialization of the dermaPACE product including hiring of new employees and continued research and development of non-medical uses of our technology.

The continuation of our business is dependent upon raising additional capital during the fourth quarter of 2018 and into 2019 to fund operations. Management’s plans are to obtain additional capital through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, including through tender offers for our outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

In addition, we may have potential liability for certain issuances of shares of Common Stock in possible violation of federal securities laws. The issuance of shares of Common Stock underlying certain of our warrants may have been in violation of the Section 5 of the Securities Act and the rules and regulations under the Securities Act. Eligible warrantholders have not filed a claim against the Company alleging a violation of the Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of the Section 5 of the Securities Act did in fact occur, eligible warrantholders, which the Company estimates represents fewer than 10 warrantholders, would have a right to rescind their exercises of warrants and the Company may have to refund any cash amounts paid for such exercises,

which could have a materially adverse effect on the Company's financial condition.

We have a history of losses and we may continue to incur losses and may not achieve or maintain profitability.

For the nine months ended September 30, 2018, we had a net loss of $9,570,056 and used $2,271,566 of cash in operations. For the nine months ended September 30, 2017, we had a net loss of $2,760,794 and used $944,831 of cash in operations. As of September 30, 2018, we had an accumulated deficit of $114,541,440 and a total stockholders' deficit of $13,467,782. As a result of our significant research, clinical development, regulatory compliance and general and administrative expenses, we expect to incur losses as we continue to incur expenses related to commercialization of the dermaPACE System and research and development of the non-medical uses of the PACE technology. Even if we succeed in developing and commercializing the dermaPACE System or any other product candidates, we may not be able to generate sufficient revenues and we may never achieve or be able to maintain profitability.

If we are unable to successfully raise additional capital, our viability may be threatened; however, if we do raise additional capital, your percentage ownership as a shareholder could decrease and constraints could be placed on the operations of our business.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our capital stock, the issuance of convertible promissory notes, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009 and product sales. We will seek to obtain additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. We also may in the future seek to raise capital through tender offers for certain of our outstanding series of warrants, whereby we offer the holders of such warrants the opportunity to amend and exercise their warrant at a reduced exercise price until the expiration date of such tender offer in order to incentivize such holders to exercise their warrants and pay the reduced exercise price in cash. These financings could result in substantial dilution to the holders of our common stock or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern. Additionally, we will be required to make mandatory prepayments of principal to HealthTronics, Inc. on the notes payable, related parties equal to 20% of the proceeds received through the issuance or sale of any equity securities in cash or through the licensing of our patents or other intellectual property rights.

A variety of factors could impact our need to raise additional capital, the timing of any required financings and the amount of such financings. Factors that may cause our future capital requirements to be greater than anticipated or could accelerate our need for funds include, without limitation:

unanticipated expenditures in research and development or manufacturing activities;

delayed market acceptance of any approved product;

unanticipated expenditures in the acquisition and defense of intellectual property rights;

the failure to develop strategic alliances for the marketing of some of our product candidates;

additional inventory builds to adequately support the launch of new products;

unforeseen changes in healthcare reimbursement for procedures using any of our approved products;

inability to train a sufficient number of physicians to create a demand for any of our approved products;

lack of financial resources to adequately support our operations;

difficulties in maintaining commercial scale manufacturing capacity and capability;

unforeseen problems with our third party manufacturers, service providers or specialty suppliers of certain raw materials;

unanticipated difficulties in operating in international markets;

unanticipated financial resources needed to respond to technological changes and increased competition;

unforeseen problems in attracting and retaining qualified personnel;

the impact of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the PPACA) on our operations;

the impact of changes in U.S. health care law and policy on our operations;

enactment of new legislation or administrative regulations;

the application to our business of new court decisions and regulatory interpretations;

claims that might be brought in excess of our insurance coverage;

delays in timing of receipt of required regulatory approvals;

the failure to comply with regulatory guidelines; and

the uncertainty in industry demand and patient wellness behavior.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line through acquisitions. Any acquisition would likely increase our capital requirements.

Our product candidates may not be developed or commercialized successfully.

Our product candidates are based on a technology that has not been used previously in the manner we propose and must compete with more established treatments currently accepted as the standards of care. Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use.

We are subject to risks that:

- the FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- the reimbursement for our products is difficult to obtain or is too low, which can hinder the introduction and acceptance of our products in the market;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates.

In addition, our product development program may be curtailed, redirected, eliminated or delayed at any time for many reasons, including:

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;
- the inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our trials; and
- regulatory delays or other regulatory actions.

We cannot predict whether we will successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

The medical device/therapeutic product industries are highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer and more effective than any products we may develop, our commercial opportunities will be reduced or eliminated.

Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products. We face competition from established medical device, pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies, and private and public research institutions in the United States and abroad. Many of our principal competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory

approvals and marketing approved products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements, or mergers with, or acquisitions by, large and established companies, or through the development of novel products and technologies.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may develop and commercialize pharmaceutical, biotechnology or medical devices that are safer or more effective, have fewer side effects or are less expensive than any products that we may develop. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to our programs or advantageous to our business.

If our products and product candidates do not gain market acceptance among physicians, patients and the medical community, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates, they may not gain market acceptance among physicians, healthcare payers, patients and the medical community. Market acceptance will depend on our ability to demonstrate the benefits of our approved products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness. In addition, we believe market acceptance depends on the effectiveness of our marketing strategy, the pricing of our approved products and the reimbursement policies of government and third party payers. Physicians may not utilize our approved products for a variety of reasons and patients may determine for any reason that our product is not useful to them. If any of our approved products fail to achieve market acceptance, our ability to generate revenues will be limited.

We may not successfully establish and maintain licensing and/or partnership arrangements for our technology for non-medical uses, which could adversely affect our ability to develop and commercialize our non-medical technology.

Our strategy for the development, testing, manufacturing, and commercialization of our technology for non-medical uses generally relies on establishing and maintaining collaborations with licensors and other third parties. We may not be able to obtain, maintain or expand these or other licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to obtain, maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Furthermore, our licensing and collaboration arrangements are subject to counterparty risk, and to the extent the licensors or other third parties that we enter into licensing, joint venture or other collaboration arrangements with face operational, regulatory or financial difficulties, and to the extent we are unable to find suitable alternative counterparties in a timely manner, if at all, our business and results of operations could be materially adversely affected. Any failure to obtain, maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our technology for non-medical uses.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our technology for non-medical uses, including possibly the design and manufacture of product materials, potentially the obtaining of regulatory or environmental approvals and the marketing and distribution of any successfully developed products. Our collaborators also may have or acquire rights to control aspects of our product development programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we may contemplate. In addition, if any of these collaborators withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

Many of our product component materials are only produced by a single supplier for such product component. If we are unable to obtain product component materials and other products from our suppliers that we depend on for our operations, or find suitable replacement suppliers, our ability to deliver our products to market will likely be impeded, which could have a material adverse effect on us.

We depend on suppliers for product component materials and other components that are subject to stringent regulatory requirements. Many of our product component materials are only produced by a single supplier for such product component, and the loss of any of these suppliers could result in a disruption in our production. If this were to occur, it may be difficult to arrange a replacement supplier because certain of these materials may only be available from one or a limited number of sources. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. In addition, establishing additional or replacement suppliers for these materials may take a substantial period of time, as certain of these suppliers must be approved by regulatory authorities.

If we are unable to secure, on a timely basis, sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then the manufacturing of our products may be disrupted, which could increase our costs and have a material adverse effect on our business and results of operations.

We currently sell our products through distributors whose sales account for the majority of our revenues and accounts receivable. Our business and results of operations could be adversely affected by any business disruptions or credit or other financial difficulties experienced by such distributors.

A majority of our revenues, and a majority of our accounts receivable, are from distributors. Five distributors accounted for 7%, 24%, 20%, 9% and 27% of revenues for the nine months ended September 30, 2018, and 0%, 60%, 0%, 0% and 6% of accounts receivable at September 30, 2018. Three distributors accounted for 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017. Two distributors accounted for 50% and 32% of revenues for the year ended December 31, 2016, and 87% and 10% of accounts receivable at December 31, 2016. To the extent that our distributors experience any business disruptions or credit or other financial difficulties, our revenues and the collectability of our accounts receivable could be negatively impacted. If we are unable to establish, on a timely basis, relationships with new distributors, our business and results of operations could be negatively impacted.

We have entered into an agreement with companies owned by a current board member and stockholder that could delay or prevent an acquisition of our company and could result in the dilution of our shareholders in the event of our change of control.

On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc. (“PSWC”) and Premier Shockwave, Inc. (“PS”), each of which is owned by A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company. Among other terms, the agreement contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. Such provision may have the effect of delaying or deterring a change in control of us, and as a result could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. In addition, in the event we do experience a change of control, such provision may cause dilution of our existing shareholders in the event that PSWC exercises its option to require the Company to purchase all issued and outstanding shares of PSWC and the Company finances some or all of such purchase price through equity issuances.

The loss of our key management would likely hinder our ability to execute our business plan.

As a small company with thirteen employees, our success depends on the continuing contributions of our management team and qualified personnel. Turnover, transitions or other disruptions in our management team and personnel could make it more difficult to successfully operate our business and achieve our business goals and could adversely affect our results of operation and financial condition. Our success depends in large part on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical, biotechnology and medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

We face an inherent risk of liability in the event that the use or misuse of our product candidates results in personal injury or death.

The use of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims which could result in financial loss. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts or scope, to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management team and other resources, and adversely impact or eliminate the prospects for commercialization of the product candidate, or sale of the product, which is the subject of any such claim. Although we do not promote any off-label use, off-label uses of products are common and the FDA does not regulate a physician’s choice of treatment. Off-label uses of any product for which we obtain approval may subject us to additional liability.

We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.

We rely to a large extent upon information technology systems to operate our businesses, some of which are managed, hosted, provided and/or used by third parties or their vendors. We collect, store and transmit large amounts of confidential information, and we deploy and operate an array of technical and procedural controls to maintain the

confidentiality and integrity of such confidential information. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact our operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us.

We generate a portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

A portion of our revenue comes from international sources, and we anticipate that we will continue to expand our overseas operations. Engaging in international business involves a number of difficulties and risks, including:

required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;

required compliance with anti-bribery laws, data privacy requirements, labor laws and anti-competition regulations;

export or import restrictions;

various reimbursement and insurance regimes;

laws and business practices favoring local companies;

political and economic instability;

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;

foreign exchange controls; and

difficulties protecting or procuring intellectual property rights.

As we expand internationally, our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

Provisions in our Articles of Incorporation, our Bylaws and Nevada law might decrease the chances of an acquisition.

Provisions of our Articles of Incorporation and Bylaws and applicable provisions of Nevada law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Some of the following provisions in our Articles of Incorporation and Bylaws that implement these are:

stockholders may not vote by written consent;

advance notice of business to be brought is required for a meeting of the Company’s stockholders;

no cumulative voting rights for the holders of common stock in the election of directors; and

vacancies in the board of directors may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

In addition, Section 78.438 of the Nevada Revised Statutes prohibits a publicly-held Nevada corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 10% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Regulatory Risks

The results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate is safe and effective in advanced clinical trials involving large numbers of patients, we will be unable to submit the necessary application to receive regulatory approval to commercialize the product candidate. We face risks that:

the product candidates may not prove to be safe or effective;

the product candidates benefits may not outweigh its risks;

the results from advanced clinical trials may not confirm the positive results from pre-clinical studies and early clinical trials;

the FDA or comparable foreign regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than us; and

the FDA or other regulatory agencies may require additional or expanded trials and data.

We are subject to extensive governmental regulation, including the requirement of FDA approval or clearance, before our product candidates may be marketed.

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected. The FDA has determined that our technology and product candidates constitute “medical devices,” and are thus subject to review by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case applicable governmental review requirements could vary in some respects and be more lengthy and costly.

Both before and after approval or clearance of our product candidates, we and our product candidates, our suppliers and our contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

warning letters;

fines and other monetary penalties;

unanticipated expenditures;

delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;

product recall or seizure;

interruption of manufacturing or clinical trials;

operating restrictions;

injunctions; and

criminal prosecutions.

In addition to the approval and clearance requirements, numerous other regulatory requirements apply, both before and after approval or clearance, to us and our products and product candidates, our suppliers and contract manufacturers. These include requirements related to the following:

testing;

manufacturing;

quality control;

labeling;

advertising;

promotion;

distribution;

export;

reporting to the FDA certain adverse experiences associated with the use of the products; and

obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

We are also subject to inspection by the FDA and other international regulatory bodies to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA and other international regulatory bodies will not identify compliance issues that may disrupt production or distribution or require substantial resources to correct.

The FDAs requirements and international regulatory body requirements may change and additional regulations may be promulgated that could affect us, our product candidates, and our suppliers and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

Patients may discontinue their participation in our clinical studies, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Clinical trials for our product candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged to be related to our product candidates under evaluation. If a large number of patients in a study discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of the product candidate.

In addition, the time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the following:

the size of the patient population;

the nature of the clinical protocol requirements;

the availability of other treatments or marketed therapies (whether approved or experimental);

our ability to recruit and manage clinical centers and associated trials;

the proximity of patients to clinical sites; and

the patient eligibility criteria for the study.

We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.

We engage a clinical research organization (CRO) and other third party vendors to assist in the conduct of our clinical trials. There are numerous sources that are capable of providing these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials, the commercial prospects for the product could be harmed and our ability to generate product revenues would be delayed or prevented. Any failure of the CRO and other third party vendors to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services they provide for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our product and obtain regulatory approval. Problems with the timeliness or quality of the work of the CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our clinical trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

Regulatory approval of our product candidates may be withdrawn at any time.

After regulatory approval has been obtained for medical device products, the product and the manufacturer are subject to continual review, including the review of adverse experiences and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturing facilities we use to make any of our products will also be subject to periodic review and inspection by the FDA or other regulatory authorities, as applicable. The discovery of any new or previously unknown problems with the product or facility may result in restrictions on the product or facility, including withdrawal of the product from the market. We will continue to be subject to the FDA or other regulatory authority requirements, as applicable, governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our product candidates, even those that the FDA or other regulatory authority, as applicable, had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in the United States Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes on us, if any, may be.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

International sales of our products and any of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the United States will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging and labeling requirements, and import restrictions on medical devices. In addition, each country has its own tariff regulations, duties and tax requirements. The approval by foreign government authorities is unpredictable and uncertain and can be expensive. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

Prior to marketing our products in any country outside the United States, we must obtain marketing approval in that country. Approval and other regulatory requirements vary by jurisdiction and differ from the United States requirements. We may be required to perform additional pre-clinical or clinical studies even if FDA approval has been obtained.

If we fail to obtain an adequate level of reimbursement for our approved products by third party payers, there may be no commercially viable markets for our approved products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our approved products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and

healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our approved products in the international markets in which those pricing approvals are sought.

We believe that, in the future, reimbursement for any of our products or product candidates may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our products currently under development and limit our ability to sell our products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our approved products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our approved products would be impaired and our future revenues, if any, would be adversely affected.

Uncertainty surrounding and future changes to healthcare law in the United States may have a material adverse effect on us.

The healthcare regulatory environment in the United States is currently subject to significant uncertainty and the industry may in the future continue to experience fundamental change as a result of regulatory reform. In March 2010, the former U.S. President signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the PPACA), which substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the biotechnology and medical device industries. The PPACA includes, among other things, the following measures:

a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, began in 2013 but a two year moratorium has been issued for sales during 2016 and 2017, and new legislation was passed in January 2018 such that the tax will be delayed until January 1, 2020;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;

payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;

an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and

a new abbreviated pathway for the licensure of biological products that are demonstrated to be biosimilar or interchangeable with a licensed biological product.

However, some of the provisions of the PPACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges. Furthermore, President Trump has vowed to repeal the PPACA, and it is uncertain whether new legislation will be enacted to replace the PPACA. On January 20, 2017, President Trump signed an executive order stating that the administration intended to seek prompt repeal of the healthcare reform law, and, pending repeal, directed the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the healthcare reform law. On October 12, 2017, President Trump signed another executive order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the healthcare reform law. The U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In the coming years, there may continue to be additional proposals relating to the reform of the United States healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations and financial condition.

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in the United States and other markets. We could experience an adverse impact on our operating results due to increased pricing pressure these markets. Governments, hospitals and other third party payors could reduce the amount of approved reimbursement for

our products or deny coverage altogether. Reductions in reimbursement levels or coverage or other cost-containment measures could adversely affect our future operating results.

If we fail to comply with the United States Federal Anti-Kickback Statute, False Claims Act and similar state laws, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other Federal healthcare program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the Federal Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by Federal healthcare programs, but instead apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in Federal healthcare programs.

Our operations may also implicate the False Claims Act. If we fail to comply with federal and state documentation, coding and billing rules, we could be subject to liability under the federal False Claims Act, including criminal and/or civil penalties, loss of licenses and exclusion from the Medicare and Medicaid programs. The False Claims Act prohibits individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government.

All of our financial relationships with healthcare providers and others who provide products or services to Federal healthcare program beneficiaries are potentially governed by the Federal Anti-Kickback Statute, False Claims Act and similar state laws. We believe our operations are in compliance with the Federal Anti-Kickback Statute, False Claims Act and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the Federal Anti-Kickback Statute, False Claims Act or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

Failure to comply with the HIPAA Privacy, Security and Breach Notification Regulations, as such rules become applicable to our business, may increase our operational costs.

The HIPAA privacy and security regulations establish comprehensive federal standards with respect to the uses and disclosures of PHI by certain entities including health plans and health care providers, and set standards to protect the confidentiality, integrity and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including, for example: the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient; a patients right to access, amend and receive an accounting of certain disclosures of PHI;the content of notices of privacy practices describing how PHI is used and disclosed and individuals rights with respect to their PHI; and implementation of administrative, technical and physical safeguards to protect privacy and security of PHI. We anticipate that, as we expand our dermaPACE business, we will in the future be a covered entity under HIPAA. We intend to adopt policies and procedures to comply with the Privacy Rule, the Security Rule and the HIPAA statute as such regulations become applicable to our business and as such regulations are in effect at such time; however, there can be no assurance that our policies and procedures will be adequate or will prevent all incidents of non-compliance with such regulations.

The privacy regulations establish a uniform federal standard but do not supersede state laws that may be more stringent. Therefore, as we expand our dermaPACE business, we may also be required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. The federal privacy regulations restrict the ability to use or disclose certain individually identifiable patient health information, without patient authorization, for purposes other than payment, treatment or health care operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations.

The HITECH Act and its implementing regulations also require healthcare providers to notify affected individuals, the Secretary of the U.S. Department of Health and Human Services, and in some cases, the media, when PHI has been breached as defined under and following the requirements of HIPAA. Many states have similar breach notification laws. In the event of a breach, to the extent such regulations are applicable to our business, we could incur operational and financial costs related to remediation as well as preparation and delivery of the notices, which costs could be substantial. Additionally, HIPAA, the HITECH Act, and their implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, private parties may also seek damages under state

laws for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, amendments to HIPAA provide that the state Attorneys General may bring an action against a covered entity for a violation of HIPAA. As we expand our business such that federal and state laws regarding PHI and privacy apply to our operations, any noncompliance with such regulations could have a material adverse effect on our business, results of operations and financial condition.

We face periodic reviews and billing audits from governmental and private payors and these audits could have adverse results that may negatively impact our business.

As a result of our participation in the Medicare and Medicaid programs, we are subject to various governmental reviews and audits to verify our compliance with these programs and applicable laws and regulations. We also are subject to audits under various government programs in which third-party firms engaged by the Centers for Medicare & Medicaid Services conduct extensive reviews of claims data and medical and other records to identify potential improper payments under the Medicare program. Private pay sources also reserve the right to conduct audits. If billing errors are identified in the sample of reviewed claims, the billing error can be extrapolated to all claims filed which could result in a larger overpayment than originally identified in the sample of reviewed claims. Our costs to respond to and defend reviews and audits may be significant and could have a material adverse effect on our business, financial condition, results of operations and cash flows. Moreover, an adverse review or audit could result in:

required refunding or retroactive adjustment of amounts we have been paid by governmental or private payors.

state or Federal agencies imposing fines, penalties and other sanctions on us.

loss of our right to participate in the Medicare program, state programs, or one or more private payor networks. or

damage to our business and reputation in various markets.

Any one of these results could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Product quality or performance issues may be discovered through ongoing regulation by the FDA and by comparable international agencies, as well as through our internal standard quality process.

The medical device industry is subject to substantial regulation by the FDA and by comparable international agencies. In addition to requiring clearance or approval to market new or improved devices, we are subject to ongoing regulation as a device manufacturer. Governmental regulations cover many aspects of our operations, including quality systems, marketing and device reporting. As a result, we continually collect and analyze information about our product quality and product performance through field observations, customer feedback and other quality metrics. If we fail to comply with applicable regulations or if post market safety issues arise, we could be subject to enforcement sanctions, our promotional practices may be restricted, and our marketed products could be subject to recall or otherwise impacted. Each of these potential actions could result in a material adverse effect on our business, operating results and financial condition.

The use of hazardous materials in our operations may subject us to environmental claims or liability.

We conduct research and development and manufacturing operations in our facility. Our research and development process may, at times, involve the controlled use of hazardous materials and chemicals. We may conduct experiments in which we may use small quantities of chemicals, including those that are corrosive, toxic and flammable. The risk of accidental injury or contamination from these materials cannot be eliminated. We do not maintain a separate insurance policy for these types of risks. In the event of an accident or environmental discharge or contamination, we may be held liable for any resulting damages, and any liability could exceed our resources. We are subject to Federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant.

Risks Related to Intellectual Property

The protection of our intellectual property is critical to our success and any failure on our part to adequately protect those rights could materially adversely affect our business.

Our commercial success depends to a significant degree on our ability to:

obtain and/or maintain protection for our product candidates under the patent laws of the United States and other countries;

defend and enforce our patents once obtained;

obtain and/or maintain appropriate licenses to patents, patent applications or other proprietary rights held by others with respect to our technology, both in the United States and other countries;

maintain trade secrets and other intellectual property rights relating to our product candidates; and

operate without infringing upon the patents, trademarks, copyrights and proprietary rights of third parties.

The degree of intellectual property protection for our technology is uncertain, and only limited intellectual property protection may be available for our product candidates, which may prevent us from gaining or keeping any competitive advantage against our competitors. Although we believe the patents that we own or license, and the patent applications that we own, generally provide us a competitive advantage, the patent positions of biotechnology, biopharmaceutical and medical device companies are generally highly uncertain, involve complex legal and factual questions and have been the subject of much litigation. Neither the United States Patent & Trademark Office nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Further, a court or other government agency could interpret our patents in a way such that the patents do not adequately cover our current or future product candidates. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon trade secrets and unpatented proprietary know-how and continuing technological innovation in developing our products, especially where we do not believe patent protection is appropriate or obtainable. We seek to protect this intellectual property, in part, by generally requiring our employees, consultants, and current and prospective business partners to enter into confidentiality agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants, researchers, and advisors who we expect to work on our products and product candidates to agree to disclose and assign to us all inventions conceived during the work day, developed using our property or which relate to our business. We may lack the financial or other resources to successfully monitor and detect, or to enforce our rights in respect of, infringement of our rights or breaches of these confidentiality agreements. In the case of any such undetected or unchallenged infringements or breaches, these confidentiality agreements may not provide us with meaningful protection of our trade secrets and unpatented proprietary know-how or adequate remedies. In addition, others may independently develop technology that is similar or equivalent to our trade secrets or know-how. If any of our trade secrets, unpatented know-how or other confidential or proprietary information is divulged to third parties, including our competitors, our competitive position in the marketplace could be harmed and our ability to sell our products successfully could be severely compromised. Enforcing a claim that a party illegally obtained and is using trade secrets that have been licensed to us or that we own is also difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could have a material adverse effect on our business. Moreover, some of our academic institution licensees, evaluators, collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to protect our proprietary information or obtain patent protection in the future may be impaired, which could have a material adverse effect on our business.

In particular, we cannot assure you that:

we or the owners or other inventors of the patents that we own or that have been licensed to us, or that may be issued or licensed to us in the future, were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies upon which we rely;

others will not independently develop similar or alternative technologies or duplicate any of our technologies;

any of our patent applications will result in issued patents;

the patents and patent applications that we own or that have been licensed to us, or that may be issued or licensed to us in the future, will provide a basis for commercially viable products or will provide us with any competitive advantages, or will not be challenged by third parties;

the patents and patent applications that have been licensed to us are valid and enforceable;

we will develop additional proprietary technologies that are patentable;

we will be successful in enforcing the patents that we own or license and any patents that may be issued or licensed to us in the future against third parties;

the patents of third parties will not have an adverse effect on our ability to do business; or

our trade secrets and proprietary rights will remain confidential.

Accordingly, we may fail to secure meaningful patent protection relating to any of our existing or future product candidates or discoveries despite the expenditure of considerable resources. Further, there may be widespread patent infringement in countries in which we may seek patent protection, including countries in Europe and Asia, which may instigate expensive and time consuming litigation that could adversely affect the scope of our patent protection. In addition, others may attempt to commercialize products similar to our product candidates in countries where we do not have adequate patent protection. Failure to obtain adequate patent protection for our product candidates, or the failure by particular countries to enforce patent laws or allow prosecution for alleged patent infringement, may impair our ability to be competitive. The availability of infringing products in markets where we have patent protection, or the availability of competing products in markets where we do not have adequate patent protection, could erode the market for our product candidates, negatively impact the prices we can charge for our product candidates, and harm our reputation if infringing or competing products are manufactured to inferior standards.

Patent applications owned by us or licensed to us may not result in issued patents, and our competitors may commercialize the discoveries we attempt to patent.

The patent applications that we own and that have been licensed to us, and any future patent applications that we may own or that may be licensed to us, may not result in the issuance of any patents. The standards that the United States Patent & Trademark Office and foreign patent agencies use to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to the type and scope of patent claims to which we may in the future be entitled under our license agreements or that may be issued to us in the future. These applications may not be sufficient to meet the statutory requirements for patentability and, therefore, may not result in enforceable patents covering the product candidates we want to commercialize. Further, patent applications in the United States that are not filed in other countries may not be published or generally are not published until at least 18 months after they are first filed, and patent applications in certain foreign countries generally are not published until many months after they are filed. Scientific and patent publication often occurs long after the date of the scientific developments disclosed in those publications. As a result, we cannot be certain that we will be the first creator of inventions covered by our patents or applications, or the first to file such patent applications. As a result, our issued patents and our patent applications could become subject to challenge by third parties that created such inventions or filed patent applications before us or our licensors, resulting in, among other things, interference proceedings in the United States Patent &Trademark Office to determine priority of discovery or invention. Interference proceedings, if resolved adversely to us, could result in the loss of or significant limitations on patent protection for our products or technologies. Even in the absence of interference proceedings, patent applications now pending or in the future filed by third parties may prevail over the patent applications that may be owned by us or licensed to us or that we may file in the future, or may result in patents that issue alongside patents issued to us or our licensors or that may be issued or licensed to us in the future, leading to uncertainty over the scope of the patents owned by us or licensed to us or that may in the future be owned by us or impede our freedom to practice the claimed inventions.

Our patents may not be valid or enforceable and may be challenged by third parties.

We cannot assure you that the patents that have been issued or licensed to us would be held valid by a court or administrative body or that we would be able to successfully enforce our patents against infringers, including our competitors. The issuance of a patent is not conclusive as to its validity or enforceability, and the validity and enforceability of a patent is susceptible to challenge on numerous legal grounds, including the possibility of reexamination proceedings brought by third parties in the United States Patent & Trademark Office against issued patents and similar validity challenges under foreign patent laws. Challenges raised in patent infringement litigation brought by us or against us may result in determinations that patents that have been issued to us or licensed to us or any patents that may be issued to us or our licensors in the future are invalid, unenforceable or otherwise subject to limitations. In the event of any such determinations, third parties may be able to use the discoveries or technologies claimed in these patents without paying licensing fees or royalties to us, which could significantly diminish the value of our intellectual property and our competitive advantage. Even if our patents are held to be enforceable, others may be able to design around our patents or develop products similar to our products that are not within the scope of any of our patents.

In addition, enforcing the patents that we own or license and any patents that may be issued to us in the future against third parties may require significant expenditures regardless of the outcome of such efforts. Our inability to enforce our patents against infringers and competitors may impair our ability to be competitive and could have a material adverse effect on our business.

Issued patents and patent licenses may not provide us with any competitive advantage or provide meaningful protection against competitors.

The discoveries or technologies covered by issued patents we own or license may not have any value or provide us with a competitive advantage, and many of these discoveries or technologies may not be applicable to our product candidates at all. We have devoted limited resources to identifying competing technologies that may have a competitive advantage relative to ours, especially those competing technologies that are not perceived as infringing on our intellectual property rights. In addition, the standards that courts use to interpret and enforce patent rights are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, we cannot be certain as to how much protection, if any, will be afforded by these patents with respect to our products if we, our licensees or our licensors attempt to enforce these patent rights and those rights are challenged in court.

The existence of third party patent applications and patents could significantly limit our ability to obtain meaningful patent protection. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from pursuing research, development or commercialization of product candidates or may be required to obtain licenses, if available, to these patents or to develop or obtain alternative technology. If another party controls patents or patent applications covering our product candidates, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our product candidates or we may be required to pay royalties, which could be substantial, to obtain licenses to use those patents or patent applications.

In addition, issued patents may not provide commercially meaningful protection against competitors. Other parties may seek and/or be able to duplicate, design around or independently develop products having effects similar or identical to our patented product candidates that are not within the scope of our patents.

Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the protection we have under patents issued outside of the United States. We do not have patent protection for our product candidates in a number of our target markets. The failure to obtain adequate patent protection for our product candidates in any country would impair our ability to be commercially competitive in that country.

The ability to market the products we develop is subject to the intellectual property rights of third parties.

The biotechnology, biopharmaceutical and medical device industries are characterized by a large number of patents and patent filings and frequent litigation based on allegations of patent infringement. Competitors may have filed patent applications or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Third parties may claim that our products or related technologies infringe their patents or may claim that the products of our suppliers, manufacturers or contract service providers that produce our devices infringe on their intellectual property. Further, we, our licensees or our licensors, may need to participate in interference, opposition, protest, reexamination or other potentially adverse proceedings in the United States Patent & Trademark Office or in similar agencies of foreign governments with regards to our patents, patent applications, and intellectual property rights. In addition, we, our licensees or our licensors may need to initiate suits to protect our intellectual property rights.

Litigation or any other proceeding relating to intellectual property rights, even if resolved in our favor, may cause us to incur significant expenses, divert the attention of our management and key personnel from other business concerns and, in certain cases, result in substantial additional expenses to license technologies from third parties. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An unfavorable outcome in any patent infringement suit or other adverse intellectual property proceeding could require us to pay substantial damages, including possible treble damages and attorneys' fees, cease using our technology or developing or marketing our products, or require us to seek licenses, if available, of the disputed rights from other parties and potentially make significant payments to those parties. There is no guarantee that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms. Even if we are able to obtain rights to a third party's patented intellectual property, those rights may be nonexclusive and, therefore, our competitors may obtain access to the same intellectual property. Ultimately, we may be unable to commercialize our product candidates or may have to cease some of our business operations as a result of patent infringement claims, which could materially harm our business. We cannot guarantee that our products or technologies will not conflict with the intellectual property rights of others.

If we need to redesign our products to avoid third party patents, we may suffer significant regulatory delays associated with conducting additional clinical studies or submitting technical, clinical, manufacturing or other information related to any redesigned product and, ultimately, in obtaining regulatory approval. Further, any such redesigns may result in less effective and/or less commercially desirable products, if the redesigns are possible at all.

Additionally, any involvement in litigation in which we, our licensees or our licensors are accused of infringement may result in negative publicity about us or our products, injure our relations with any then-current or prospective customers and marketing partners, and cause delays in the commercialization of our products.

Risks Related to our Common Stock

Our stock price is volatile.

The market price of our common stock is volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

our ability to obtain additional financing and, if available, the terms and conditions of the financing;

changes in the timing of on-going clinical trial enrollment, the results of our clinical trials and regulatory approvals for our product candidates or failure to obtain such regulatory approvals;

changes in our industry;

additions or departures of key personnel;

sales of our common stock;

our ability to execute our business plan;

operating results that fall below expectations;

period-to-period fluctuations in our operating results;

new regulatory requirements and changes in the existing regulatory environment; and

general economic conditions and other external factors.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

There is currently a limited trading market for our common stock and we cannot predict how liquid the market might become.

To date, there has been a limited trading market for our common stock and we cannot predict how liquid the market for our common stock might become. Our common stock is quoted on the Over-the-Counter market ("OTCQB"), which is an inter-dealer market that provides significantly less liquidity than the New York Stock Exchange or the Nasdaq Stock Market. The quotation of our common stock on the OTCQB does not assure that a meaningful, consistent and liquid trading market exists. The market price for our common stock is subject to volatility and holders of our common stock may be unable to resell their shares at or near their original purchase price, or at any price. In the absence of an active trading market:

investors may have difficulty buying and selling, or obtaining market quotations for our common stock;

market visibility for our common stock may be limited; and

a lack of visibility for our common stock may have a depressive effect on the market for our common stock.

Trading for our common stock is limited under the SECs penny stock regulations, which has an adverse effect on the liquidity of our common stock.

The trading price of our common stock is less than $5.00 per share and, as a result, our common stock is considered a “penny stock,” and trading in our common stock is subject to the requirements of Rule 15g-9 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Under this rule, broker-dealers who recommend low-priced securities to persons other than established customers and accredited investors must satisfy special sales practice requirements. Generally, the broker-dealer must make an individualized written suitability determination for the purchaser and receive the purchaser’s written consent prior to the transaction.

Regulations of the Securities and Exchange Commission (the “SEC”) also require additional disclosure in connection with any trades involving a “penny stock,” including the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and its associated risks. These requirements severely limit the liquidity of securities in the secondary market because only a few brokers or dealers are likely to undertake these compliance activities. Compliance with these requirements may make it more difficult for holders of our Common Stock to resell their shares to third parties or to otherwise dispose of them in the market.

As an issuer of “penny stock”, the protection provided by the federal securities laws relating to forward looking statements does not apply to us.

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our board of directors has the right, without stockholder approval, to issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the voting power and equity interest of the holders of common stock, which could be issued with the right to more than one vote per share, and could be utilized as a method of discouraging, delaying or preventing a change of control. The possible negative impact on takeover attempts could adversely affect the price of our common stock.

On January 12, 2016, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series B Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 293 shares of our preferred stock as Series B Convertible Preferred Stock. The 293 shares of Series B Convertible Preferred Stock were converted to 3,657,278 shares of Common Stock on April 29, 2016. Although we have no shares of preferred stock currently outstanding and no present intention to issue any shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

We have never held an annual meeting for the election of directors.

Pursuant to the provisions of the Nevada Revised Statutes (the “NRS”), directors are to be elected at the annual meeting of the stockholders. Pursuant to the NRS and our bylaws, our board of directors is granted the authority to fix the date, time and place for annual stockholder meetings. No date, time or place has yet been fixed by our board for the holding of an annual stockholder meeting. Pursuant to the NRS and our bylaws, each of our directors holds office after the expiration of his term until a successor is elected and qualified, or until the director resigns or is removed. Under the provisions of the NRS, if an election of our directors has not been made by our stockholders within 18 months of the last such election, then an application may be made to the Nevada district court by stockholders holding a minimum of 15% of our outstanding stockholder voting power for an order for the election of directors in the manner provided in the NRS.

We have not sought an advisory stockholder vote to approve the compensation of our named executive officers.

Rule 14a-21 under the Exchange Act requires us to seek a separate stockholder advisory vote at our annual meeting at which directors are elected to approve the compensation of our named executive officers, not less frequently than once every three years (say-on-pay vote), and, at least once every six years, to seek a separate stockholder advisory vote on the frequency with which we will submit advisory say-on-pay votes to our stockholders (say-on-frequency vote). In 2013, the year in which Rule 14a-21 became applicable to smaller reporting companies, and in 2014, we did not submit to our stockholders a say-on-pay vote to approve an advisory resolution regarding our compensation program for our named executive officers, or a say-on-frequency vote. Consequently, the board of directors has not considered the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers.

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USE OF PROCEEDS

All net proceeds from the sale of the shares of Common Stock covered by this prospectus will go to the selling stockholders. We will receive none of the proceeds from the sale of the shares of Common Stock covered by this prospectus by the selling stockholders. We may receive proceeds upon the exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. If all of such warrants are exercised for cash in full, the proceeds would be approximately $4,630,000. We intend to use the net proceeds of any such warrant exercises, if any, for working capital purposes. We can make no assurances that any of the warrants will be exercised, or if exercised, that they will be exercised for cash, the quantity which will be exercised or in the period in which they will be exercised.

SELLING STOCKHOLDERS

The following table presents information regarding the selling stockholders. The selling stockholders may sell up to 61,128,147 shares of Common Stock (including shares issuable upon exercise of the Class L warrants and Series A warrants). Beneficial ownership as reported in the below table has been determined in accordance with Rule 13d-3 of the Exchange Act and is based on 155,533,303 shares of common stock issued and outstanding as of December 3, 2018.

The selling stockholders identified in this prospectus may offer the shares of our Common Stock at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. See “Plan of Distribution” for additional information.

Unless otherwise indicated, we believe, based on information supplied by the following persons, that the persons named in the table below have sole voting and investment power with respect to all shares of Common Stock that they beneficially own. The registration of the offered shares does not mean that any or all of the selling stockholders will offer or sell any shares of Common Stock.

		Number of Shares beneficially owned prior to this offering		Number of Shares being offered (1)		Number of Shares beneficially owned after this offering	
	Name of Beneficial Owner	Number	Percent	Number	Percent	Number	Percent
	Directors and Executive Officers:						
(11)	Kevin A. Richardson, II	17,564,160	10.6%	4,724,626	2.9%	12,839,534	7.8%
(10)	A. Michael Stolarski	16,789,333	10.0%	225,000	*	16,564,333	10.0%
	Principal and/or Selling Shareholders:						
(2)	Jerome Gildner	13,333,334	8.2%	6,666,667	4.1%	6,666,667	4.1%
(5)	John McDermott	12,575,756	7.8%	5,833,333	3.6%	6,742,423	4.2%
(5)	James McGraw	11,610,694	7.3%	4,579,167	2.9%	7,031,527	4.4%
(5)	Nicholas Carosi III	11,818,182	7.4%	4,000,000	2.5%	7,818,182	4.9%
(5)	Todd W Arbiture	5,833,333	3.7%	3,750,000	2.4%	2,083,333	1.3%
(5)	Horberg Enterprises LP	5,000,001	3.1%	3,333,334	2.1%	1,666,667	1.0%
(9)	Michael Nemelka	4,730,336	3.0%	3,255,336	2.1%	1,475,000	*
(4)	Nainoor Thakore	5,833,334	3.7%	2,916,667	1.8%	2,916,667	1.8%
(8)	Bradley Richmond	3,103,034	2.0%	2,887,934	1.8%	215,100	*
(2)	Howard Bialick And Mary Beth Bialick	2,350,000	1.5%	2,350,000	1.5%	-	*
(5)	Ian Miller	3,916,667	2.5%	2,250,000	1.4%	1,666,667	1.1%
(4)	Lynn A. Anderson	3,800,000	2.4%	1,900,000	1.2%	1,900,000	1.2%
(2)	Lawrence Wert	1,666,667	1.1%	1,666,667	1.1%	-	*
(5)	Tyler J. Anderson	2,250,001	1.4%	1,333,334	*	916,667	*
(4)	Kerri Johnson	2,333,334	1.5%	1,166,667	*	1,166,667	*
(2)	James A. Lambert	1,000,000	*	1,000,000	*	-	*
(4)	Debra L. Miller	1,666,666	1.1%	833,333	*	833,333	*
(4)	Howard Bialick	1,666,666	1.1%	833,333	*	833,333	*
(5)	John Willis	1,250,001	*	833,334	*	416,667	*
(5)	Jeramy Fisher	750,001	*	583,334	*	166,667	*
(2)	James Groth	416,667	*	416,667	*	-	*
(4)	Scott Hodges	833,334	*	416,667	*	416,667	*
(4)	Siltstone Capital Partners LP	833,334	*	416,667	*	416,667	*
(2)	Dennis Holman	400,000	*	400,000	*	-	*
(2)	James P Geiskopf	383,333	*	383,333	*	-	*
(2)	Jodarr Pty Ltd	312,500	*	312,500	*	-	*
(2)	Marianna Reis	266,667	*	266,667	*	-	*

(7)	MAZ Partners LP	251,356	*	251,356	*	-	*
(2)	Brian Keller And Debbie Keller	200,000	*	200,000	*	-	*
(2)	Eric Love	200,000	*	200,000	*	-	*
(4)	Roberto Nascinento	400,000	*	200,000	*	200,000	*
(2)	Cor Clearing Custodian George Naumov Ira	166,667	*	166,667	*	-	*
(2)	Darren Banks	125,000	*	125,000	*	-	*
(3)	Vesselin Mihaylov	125,000	*	125,000	*	-	*
(6)	Joseph Chiarelli	280,000	*	100,000	*	180,000	*
(7)	Arthur Motch IV	62,746	*	62,746	*	-	*
(7)	Barbara Miner	50,269	*	50,269	*	-	*
(2)	Cor Clearing Custodian George Naumov Roth Ira	50,000	*	50,000	*	-	*
(2)	Cor Clearing Custodian George Naumov Sep Ira	50,000	*	50,000	*	-	*
(7)	Paul Miner	12,542	*	12,542	*	-	*
TOTAL SHARES FOR RESALE:				61,128,147			

(1) Applicable percentage ownership is based on 155,533,303 shares of common stock outstanding as of December 3, 2018. "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of December 3, 2018. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.

(2) Shares issuable upon the exercise of certain warrants issued pursuant to 2016 Equity Offering.

(3) Shares issuable upon the exercise of certian warrants issued pursuant to 2016 Equity Offering for the placement agent fee.

(4) Shares outstanding and shares issuable upon the exercise of certain warrants issued pursuant to August 2016 Private Placement.

(5) Shares outstanding and shares issuable upon the exercise of certain warrants issued pursuant to August 2016 Private Placement. Shares issuable upon the exercise of certain warrants issued pursuant to 2016 Equity Offering.

(6) Shares issuable upon the exercise of certain warrants issued pursuant to the March 2014 Private Placement.

(7) Shares issuable upon the exercise of certain Series A Warrants.

(8) Shares issuable upon the exercise of certain warrants issued pursuant to March 2014 Private Placement for the placement agent fee. Shares outstanding and shares issuable upon the exercise of certain warrants issued pursuant to August 2016 Private Placement for the placement agent fee. Shares issuable upon the exercise of certain warrants issued pursuant to 2016 Equity Offering for the placement agent fee.

(9) Shares issuable upon the exercise of certain warrants issued pursuant to the March 2014 Private Placement. Shares outstanding and shares issuable upon the exercise of certain warrants issued pursuant to August 2016 Private Placement. Shares issuable upon the exercise of certain warrants issued pursuant to 2016 Equity Offering. Shares issuable upon the exercise of certain Series A Warrants.

(10) Shares outstanding and issuable upon the exercise of certain warrants issued pursuant to August 2016 Private Placement and 241,182 shares acquired over three years ago based on the records of the Company. Shares outstanding issued pursuant to Series A Warrant Conversion and 1,113,881 shares acquired over three years ago based on records of the Company. Shares issuable upon the exercise of certain warrants issued pursuant to 2016 Equity Offering.

(11) Shares outstanding issued pursuant to March 2014 Private Placement and shares issuable upon the exercise of certain warrants issued pursuant to the March 2014 Private Placement.

The following is a description, in chronological order, of transactions between the Company and the selling stockholders related to the Common Stock held by such selling stockholders and Common Stock underlying Series A warrants and Class L warrants held by such selling stockholders, the resales of which are being registered by this Registration Statement:

March 2014 Private Placement and Offering of 18% Convertible Promissory Notes

On March 17, 2014, the Company completed a private placement of securities to ten institutional and individual accredited investors for an aggregate total purchase price of $9,280,000 (the “March 2014 Private Placement”). At the closing of the March 2014 Private Placement, the Company issued an aggregate total of (i) 6,210,000 shares of Common Stock, (ii) 6,175 shares of Series A Convertible Preferred Stock, which were convertible into shares of Common Stock, (iii) 23,200,000 Series A warrants to purchase shares of Common Stock at an exercise price of $0.50 per share (which exercise price was adjusted as of March 11, 2016 pursuant to the terms of the Series A warrants to

$0.0334 as a result of the 2016 Equity Offering (defined below)), which warrants vested upon issuance and expire after five years, and (iv) 13,920,000 Series B warrants to purchase shares of Common Stock at an exercise price of $1.50 per share, which warrants vested upon issuance and expired after one year. In addition, at the closing of the private placement, the Company issued Newport Coast Securities, Inc., the placement agent for the private placement, and Oppenheimer & Co. Inc., the former placement agent, 696,000 Series A warrants and 417,600 Series B warrants, with identical terms to the warrants issued to investors in the private placement, as part of such placement agents' compensation for the March 2014 Private Placement. As part of the March 2014 Private Placement, the Company entered into a registration rights agreement, dated March 17, 2014, with the investors in the private placement, which agreement included a registration right for the Common Stock issued in the March 2014 Private Placement and issuable upon the conversion or exercise, as applicable, of the Series A Convertible Preferred Stock, Series A warrants and Series B warrants, until the date on which such investor may sell all of registrable securities held without restriction (including volume restrictions) pursuant to Rule 144 and without the need for current public information required by Rule 144(c)(1) or the date on which the investor has sold all of registrable securities held by such investor.

In addition, between January 24, 2014 and March 7, 2014, the Company entered into subscription agreements with certain accredited investors for the purchase of unsecured 18% convertible promissory notes (the "18% Convertible Promissory Notes"). In March 2014, the Company closed the 18% Convertible Promissory Notes offering and issued an aggregate $815,000 principal amount of the 18% Convertible Promissory Notes. Upon issuance, the 18% Convertible Promissory Notes had a nine month term from the subscription date and could be converted by the noteholder into Common Stock at any time during the term at $0.55 per share. The March 2014 Private Placement was a "qualified financing" under the terms of the 18% Convertible Promissory Notes. As a result, on March 17, 2014, at the time of the closing of the March 2014 Private Placement, the unpaid principal and interest balance of the 18% Convertible Promissory Notes, which in the aggregate totaled $822,168, was automatically converted into 1,644,337 shares of Common Stock, 2,055,421 Series A warrants and 1,233,252 Series B warrants (the "18% Convertible Note Conversion").

In November and December 2014, the holders of Series A Convertible Preferred Stock from the March 2014 Private Placement converted 5,010 shares of Series A Convertible Preferred Stock into 10,020,000 shares of Common Stock, and on January 6, 2015, the holders of Series A Convertible Preferred Stock from the March 2014 Private Placement converted the remaining 1,165 shares of Series A Convertible Preferred Stock into 2,330,000 shares of common stock (together, the "Series A Convertible Preferred Stock Conversion"). As a result, as of January 6, 2015, there were no outstanding shares of Series A Convertible Preferred Stock.

On March 17, 2015, all Series B warrants issued by the Company from the March 2014 Private Placement and 18% Convertible Note Conversion expired unexercised.

On January 13, 2016, the Company entered into an exchange agreement (the "Exchange Agreement") with certain holders of the Series A warrants issued in the March 2014 Private Placement and in the 18% Convertible Note Conversion, pursuant to which such holders exchanged such Series A warrants for either (i) shares of Common Stock or (ii) shares of Common Stock and shares of the Company's Series B Convertible Preferred Stock. The exchange was based on the exchange ratio whereby one Series A warrant was exchanged for 0.4685 shares of Common Stock. Holders who, as a result of the exchange, would own in excess of 9.99% of the outstanding Common Stock (the "Ownership Threshold") received a mixture of Common Stock and shares of Series B Convertible Preferred Stock, namely Common Stock up to the Ownership Threshold and shares of Series B Convertible Preferred Stock beyond the Ownership Threshold (with the total shares of Common Stock and Series B Convertible Preferred Stock issued to such holders based on the same exchange ratio). The relative rights, preferences, privileges and limitations of the Series B Convertible Preferred Stock were as set forth in the Company's Certificate of Designation of Series B Convertible Preferred Stock, which was filed with the Secretary of State of the State of Nevada on January 12, 2016 (the "Series B Certificate of Designation"). In the exchange, an aggregate number of 23,701,428 Series A warrants, which represented 22,437,500 Series A warrants initially issued as part of the March 2014 Private Placement and 1,263,928 Series A warrants initially issued as part of the 18% Convertible Note Conversion, were exchanged for 7,447,954 shares of Common Stock and 293 shares of Series B Convertible Preferred Stock (the "Series A Warrant Conversion"). Pursuant to the Series B Certificate of Designation, each share of Series B Convertible Preferred Stock was convertible into shares of Common Stock at an initial rate of one share of Series B Convertible Preferred Stock for 12,500 shares of Common Stock, which conversion rate was subject to further adjustment as set forth in the Series B Certificate of Designation. All 293 shares of Series B Convertible Preferred Stock were converted to 3,657,278 shares of Common Stock on April 29, 2016 (the "Preferred Stock Conversion"). In connection with entering into the Exchange Agreement, the Company also entered into a registration rights agreement, dated January 13, 2016, with the holders of the Series A warrants who participated in the exchange, which agreement included a registration right for the Common Stock issued as part of the exchange or issuable upon the conversion of the Series B Convertible Preferred Stock, until the date on which such investor may sell all of registrable securities held without restriction (including volume restrictions) pursuant to Rule 144 and without the need for current public information required by Rule 144(c)(1) or the date on which the investor has sold all of registrable securities held by such investor.

Between the date of their issuance on March 17, 2014 and the date of this prospectus, 893,000 of the Series A warrants issued as part of the 2014 March Private Placement and not exchanged in the January 13, 2016 transaction have been exercised on a cashless basis. Between the date of their issuance on March 17, 2014 and the date of this prospectus, 125,246 of the Series A warrants issued as part of the 18% Convertible Note Conversion and not exchanged in the January 13, 2016 transaction have been exercised on a cashless basis and 75,666 of the Series A warrants issued as part of the 18% Convertible Note Conversion and not exchanged in the January 13, 2016 transaction have been exercised on a cash basis.

This Registration Statement registers the resale of the following securities held by the selling stockholders issued as a result of the transactions described in this section: (i) 423,705 shares of Common Stock held by the selling stockholders that continue to have registration rights under the March 17, 2014 registration rights agreement or the January 13, 2016 registration rights agreement; (ii) 350,000 shares of Common Stock underlying Series A warrants issued to investors in the March 2014 Private Placement that remain outstanding; (iii) 215,100 shares of Common Stock underlying Series A warrants issued to the placement agent in the March 2014 Private Placement that remain outstanding;and (iv) 590,582 shares of Common Stock underlying Series A warrants that remain outstanding from the 18% Convertible Note Conversion.

2016 Equity Offering

On March 11, 2016, April 6, 2016, and April 15, 2016, the Company issued an aggregate of 25,495,835, 3,083,334 and 1,437,501, respectively, of “units” to select accredited investors, as defined in Rule 501 promulgated under Regulation D of the Securities Act (the “Unit Purchasers”) an aggregate purchase price of $1,529,750, $185,000 and $86,200, respectively (the “2016 Equity Offering”). Each unit consisted of one share of Common Stock and one Class L warrant to purchase one share of Common Stock at an exercise price of $0.08 per share. The 30,016,670 Class L warrants issued as part of the 2016 Equity Offering vested upon issuance and expire on March 17, 2019. In addition, at the closing of the 2016 Equity Offering, the Company paid Newport Coast Securities, Inc., the placement agent for the 2016 Equity Offering, cash compensation based on the gross proceeds of the private placement and issued the placement agent 3,001,667 Class L warrants.

The 2016 Equity Offering was registered pursuant to a Registration Statement on Form S-1 (Registration No. 333-208676), which was declared effective on February 16, 2016, but which as of the date of this prospectus is no longer current. As of the date of this prospectus, certain holders have exercised 1,933,333 Class L warrants issued in the 2016 Equity Offering and the placement agent has exercised 2,043,333 Class L warrants issued as compensation for the 2016 Equity Offering. Certain of the investors in the 2016 Equity Offering that exercised the Class L warrants they received in such offering as well as the placement agent, with respect to the Class L warrants issued as compensation for the 2016 Equity Offering and exercised by the placement agent, have rescission rights. See “Risk Factors—Our recurring losses from operations and dependency upon future issuances of equity or other financing to fund ongoing operations have raised substantial doubts as to our ability to continue as a going concern. We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so, and/or the terms of any financings may not be advantageous to us.”

As of the date of this prospectus, 28,083,337 Class L warrants issued to investors in the 2016 Equity Offering remain outstanding and 958,334 Class L warrants issued to the placement agent for the 2016 Equity Offering remain outstanding. This Registration Statement registers the resale of the shares of Common Stock underlying such Class L warrants.

August 2016 Private Placement

On August 24, 2016, the Company entered into a Securities Purchase Agreement with certain accredited investors (the “Purchasers”) for the issuance of an aggregate total 28,300,001 shares of Common Stock for an aggregate total purchase price of $1,698,000 (the “August 2016 Private Placement”). The Company has used the proceeds from the August 2016 Private Placement for working capital and general corporate purposes. In addition, the Company, in connection with the August 2016 Private Placement, issued to the Purchasers an aggregate total of 28,300,001 Class L warrants to purchase shares of Common Stock at an exercise price of $0.08 per warrant. Each Class L warrant represents the right to purchase one share of Common Stock. The Class L warrants vested upon issuance and expire on March 17, 2019. Anthony M. Stolarski, a member of our board of directors and an existing shareholder of the Company and Michael Nemelka, the brother of a member of our board of directors and an existing shareholder of the Company,

were purchasers in the August 2016 Private Placement. At the closing of the August 2016 Private Placement, we paid WestPark Capital, Inc., the placement agent for the August 2016 Private Placement, a fee of (i) ten percent of the aggregate purchase price of the securities sold in the August 2016 Private Placement and (ii) warrants to purchase ten percent of the number of shares sold in the August 2016 Private Placement. Accordingly, the placement agent was issued Class L warrants to purchase 2,830,000 shares of Common Stock at an exercise price of $0.08 per share. As part of the August 2016 Private Placement, the Company entered into a registration rights agreement, dated August 24, 2016, with the investors in the private placement, which agreement included a registration right for the Common Stock issued in the August 2016 Private Placement and issuable upon the exercise of the Series A warrants, until the date on which such investor may sell all of registrable securities held without restriction (including volume restrictions) pursuant to Rule 144 and without the need for current public information required by Rule 144(c)(1) or the date on which the investor has sold all of registrable securities held by such investor.

In cashless exercises pursuant to Section 3(a)(9) of the Securities Act, the Purchasers have exercised 1,783,333 Class L warrants for shares of Common Stock and subsequently sold such shares pursuant to Rule 144. In a cashless exercise pursuant to Section 3(a)(9) of the Securities Act, the Placement Agent has exercised 990,500 Class L warrants and subsequently sold the shares received upon such cashless exercise pursuant to Section 4(a)(3) of the Securities Act.

This Registration Statement registers the resale of the following securities held by the selling stockholders issued as a result of the transactions described in this section: (i) 1,000,000 shares of Common Stock held by the selling stockholders that continue to have registration rights under the August 24, 2016 registration rights agreement; (ii) 26,516,668 shares of Common Stock underlying the Class L warrants issued to investors in the August 2016 Private Placement that remain outstanding; and (iii) 1,839,500 shares of Common Stock underlying the Class L warrants held by the placement agent in the August 2016 Private Placement that remain outstanding.

Other Transactions with our Selling Stockholders

This Registration Statement registers the resale of 1,150,921 shares of Common Stock that we issued to A. Micheal Stolarski as the result of private placements in 2009 and 2013.

PLAN OF DISTRIBUTION

Offering of Shares by Selling Stockholders and Upon Exercise of Warrants

We are registering the resale of shares of Common Stock issuable to the selling shareholders from time to time after the date of this prospectus. See “Selling Shareholders” for additional information. We will not receive any proceeds from the resale of shares of Common Stock by selling shareholders in this offering. We may receive proceeds upon the exercise of outstanding warrants for shares of Common Stock covered by this prospectus if the warrants are exercised for cash. See "Use of Proceeds."

As required by FINRA pursuant to Rule 5110(g)(1), neither WestPark Capital, Inc.’s warrants nor any shares of Common Stock issued upon exercise of such warrants may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date hereof, except the transfer of any security:

by operation of law or by reason of our reorganization;

to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period;

if the aggregate amount of our securities held by the placement agent or related person do not exceed 1% of the securities being offered;

that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or

the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

The selling stockholders may sell all or a portion of the shares of Common Stock held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of Common Stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;

in the over-the-counter market;

in transactions otherwise than on these exchanges or systems or in the over-the-counter market;

through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales made after the date the registration statement of which this prospectus forms a part is declared effective by the SEC;

broker-dealers may agree with a selling security holder to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares of Common Stock under Rule 144 promulgated under the Securities Act of 1933, as amended, if available, rather than under this prospectus. In addition, the selling stockholders may transfer the shares of Common Stock by other means not described in this prospectus. If the selling stockholders effect such transactions by selling shares of Common Stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the selling stockholders and any broker-dealer participating in the distribution of the shares of Common Stock may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares of Common Stock in violation of any applicable securities laws. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of Common Stock to engage in market-making activities with respect to the shares of Common Stock. All of the foregoing may affect the marketability of the shares of Common Stock and the ability of any person or entity to engage in market-making activities with respect to the shares of Common Stock.

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

The Company's Common Stock is quoted on the OTCQB under the symbol "SNWV". The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not necessarily represent actual transactions.

As of December 3, 2018, there were 155,533,303 shares of our Common Stock outstanding and approximately 135 holders of record of our Common Stock. However, we believe that there are more beneficial holders of our Common Stock as many beneficial holders hold their stock in "street name."

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	-	$0.00	-
Equity compensation plans not approved by security holders	31,673,385	$0.29	4,658,281
Total	31,673,385	$0.29	4,658,281

Stock Incentive Plans

During 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc., and certain non-statutory stock option agreements with key employees outside of the 2006 Stock Incentive Plan. The non-statutory stock option agreements have terms substantially the same as the 2006 Stock Incentive Plan. The stock options granted under the plans were nonstatutory options which vest over a period of up to four years and have a ten year term. The options were granted at an exercise price equal to the fair market value of the common stock on the date of the grant, which was approved by the board of directors of the Company.

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

MANAGEMENTS DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding our business development plans, clinical trials, regulatory reviews, timing, strategies, expectations, anticipated expenses levels, projected profits, business prospects and positioning with respect to market, demographic and pricing trends, business outlook, technology spending and various other matters (including contingent liabilities and obligations and changes in accounting policies, standards and interpretations) and express our current intentions, beliefs, expectations, strategies or predictions. These forward-looking statements are based on a number of assumptions and currently available information and are subject to a number of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections titled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" and elsewhere in this prospectus. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

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 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 have started marketing our dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

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 OssaTron, Evotron®, and orthoPACE®

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 shockwaves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

Recent Developments

On December 28, 2017, the 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.

On September 27, 2017, we entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), effective as of September 25, 2017, for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed will pay the Company an initial upfront distribution fee, with monthly upfront distribution fees payable thereafter over the following eighteen months. Profits from the joint venture are distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial upfront distribution fee was received on October 6, 2017. Monthly upfront distribution fee payments have been received through May 2018. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company received a response letter stating that the Company was in default of the agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. The Company is currently in discussions with a new partner to take over this agreement for the marketing and distribution of its products in Brazil.

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

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

name of Holistic Wellness Alliance Pte. Ltd. (“HWA”). HWA was formed as a joint venture of the Company and FKS for the manufacture, sale and distribution of the Company’s dermaPACE® and orthoPACE® devices. Under the JV Agreement, the Company and FKS each hold shares constituting fifty percent of the issued share capital of HWA. The Company provides to HWA FDA and CE approved products for an agreed cost, access to treatment protocols, training, marketing and sales materials and management expertise, and FKS provides to HWA capital, human capital and sales resources in Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam, certain reports and identification of new key opinion leaders as well as clinical trial and poster access availability. The JV Agreement also established the corporate governance of HWA, including a five-person board of directors consisting of two directors designated by the Company, two directors designated by FKS, and a third director appointed jointly by the parties. Initially, net profits under the JV Agreement shall be used to repay FKS for (i) the payment of $500,000 on June 22, 2018 to the Company for initial distribution rights in Taiwan and (ii) the cash advance to HWA per the terms of the JV Agreement. The JV Agreement includes other customary terms, including regarding the transfer of shares, indemnification and confidentiality.

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

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

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

On October 17, 2018, the Company and a vendor agreed to settle a portion of a previously incurred fee for services in Common Stock in lieu of cash. On October 17, 2018, the Company issued 426,176 shares for services rendered May 2017 through February 2018. Non-cash general and administrative expense of $15,000 and $60,000 was recorded in 2018 and 2017, respectively.

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder.

Clinical Trials and Marketing

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

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

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

The only significant difference between the two studies was the number of applications of the dermaPACE device. Study one (DERM01; n=206) prescribed four (4) device applications/treatments over a two-week period, whereas,

study two (DERM02; n=130) prescribed up to eight (8) device applications (4 within the first two weeks of randomization, and 1 treatment every two weeks thereafter up to a total of 8 treatments over a 10-week period). If the wound was determined closed by the PI during the treatment regimen, any further planned applications were not performed.

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm2 and 16cm2, inclusive. Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 Day 0), the first treatment was applied (either dermaPACE or Sham Control application). Applications with either dermaPACE or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

A total of 336 patients were enrolled in the dermaPACE studies at 37 sites. The patients in the studies were followed for a total of 24 weeks. The studies primary endpoint, wound closure, was defined as “successful” if the skin was 100% re-epithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits.

A summary of the key study findings were as follows:

Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study (p=0.320). There were 39 out of 172 (22.67%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 30 out of 164 (18.29%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, and in conjunction with the FDA agreement to analyze the efficacy analysis carried over the full 24 weeks of the study, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 61 (35.47%) dermaPACE subjects achieving complete wound closure compared with 40 (24.39%) of sham-control subjects (p=0.027). At the 24 week endpoint, the rate of wound closure in the dermaPACE® cohort was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023.

Within 6 weeks following the initial dermaPACE treatment, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control ($p<0.05$).

The proportion of patients with wound closure indicate a statistically significant difference between the dermaPACE and the control group in the proportion of subjects with the target-ulcer not closed over the course of the study (p-value=0.0346). Approximately 25% of dermaPACE® subjects reached wound closure per the study definition by day 84 (week 12). The same percentage in the control group (25%) did not reach wound closure until day 112 (week 16). These data indicate that in addition to the proportion of subjects reaching wound closure being higher in the dermaPACE® group, subjects are also reaching wound closure at a faster rate when dermaPACE is applied.

dermaPACE demonstrated superior results in the prevention of wound expansion (≥ 10% increase in wound size), when compared to the control, over the course of the study at 12 weeks (18.0% versus 31.1%; p=0.005, respectively).

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

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

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

Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which

suggests that a second course of treatment, if needed, is a clinically viable option.

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

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

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

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

Financial Overview

Since our inception, we have incurred losses from operations each year. As of September 30, 2018, we had an accumulated deficit of $114,541,440. Although the size and timing of our future operating losses are subject to significant uncertainty, we anticipate that our operating losses will continue over the next few years as we incur expenses related to commercialization of our dermaPACE system for the treatment of diabetic foot ulcers in the United States. If we are able to successfully commercialize, market and distribute the dermaPACE system, we hope to partially or completely offset these losses in the future.

Our operating losses create substantial doubt about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing will provide the necessary funding for us to continue as a going concern for the next year. See “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 products, including the uncertainty of:

the scope, rate of progress and cost of our clinical trials;

future clinical trial results;

the cost and timing of regulatory approvals;

the establishment of successful marketing, sales and distribution;

the cost and timing associated with establishing reimbursement for our products;

the effects of competing technologies and market developments; and

the industry demand and patient wellness behavior.

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth under the section entitled “Risk Factors Risks Related to Our Business”.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The

preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to the recording of the allowances for doubtful accounts, estimated reserves for inventory, estimated useful life of property and equipment, the determination of the valuation allowance for deferred taxes, the estimated fair value of warrants and 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 this registration statement on Form S-1, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, intangible assets, liabilities related to warrants issued, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

Liabilities related to Warrants Issued

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

Warrants Related to Debt Issued

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

Beneficial Conversion Feature on Convertible Debt

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

Stock-based Compensation

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

In accordance with ASC 718, Compensation Stock Compensation (formerly SFAS No. 123(R), Accounting for Stock-Based Compensation), the fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The expected terms of options granted represent the period of time that options granted are estimated to be outstanding and are derived from the contractual terms of the options granted. We amortize the fair value of each option over each options vesting period.

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

Revenues and Cost of Revenues

Revenues for the nine months ended September 30, 2018 were $1,393,271, compared to $422,199 for the same period in 2017, an increase of $971,072, or 230%. Revenues resulted primarily from sales in the United States and Europe of our dermaPACE and orthoPACE devices and related applicators. The increase in revenues for 2018 was due to the higher sale of devices and both new and refurbished applicators in the United States, Southeast Asia and Europe as compared to the same period in 2017.

Cost of revenues for the nine months ended September 30, 2018 were $515,703, compared to $141,523 for the same period in 2017. Gross profit as a percentage of revenues was 63% for the nine months ended September 30, 2018, compared to 66% for the same period in 2017. The decrease in gross profit as a percentage of revenues in 2018 was due to the higher number of devices sold in 2018, which have a lower gross margin than building new and refurbishing applicators.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2018 were $1,379,517, compared to $965,084 for the same period in 2017, an increase of $414,433, or 43%. Research and development costs include payments to third parties that relate to our products in clinical development and employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, quality assurance, and research and development departments. The increase in research and development expenses was due to increased salary and benefits related to new hires, stock-based compensation expense for stock options issued to new hires and in September 2018, accrual of bonus, and consulting fees related to reimbursement strategy which was partially offset by lower consultant costs related to the FDA submission and follow up.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2018 were $5,391,511, as compared to $1,875,891 for the same period in 2017, an increase of $3,515,620, or 187%. The increase in general and administrative expenses was due to the hiring of a president and human resources director and the related stock-based compensation expense for stock options issued, stock-based compensation for options issued in September 2018, higher travel costs, accrual of bonus, recruiting fees for open positions, higher legal and accounting fees related to SEC filings and higher consultant fees related to the commercialization of dermaPACE.

Other Income (Expense)

Other income (expense) was a net expense of $3,656,693 the nine months ended September 30, 2018, as compared to a net expense of $182,952 for the same period in 2017, an increase in other expense of $3,473,741. The increase in other expense for 2018 was mainly due to interest expense related to convertible promissory notes and notes payable, related party and was partially offset by a gain on warrant valuation adjustment.

Net Loss

Net loss for the nine months ended September 30, 2018 was $9,570,056, or ($0.06) per basic and diluted share, compared to a net loss of $2,760,794, or ($0.02) per basic and diluted share, for the same period in 2017, an increase in the net loss of $6,809,262. The increase in the net loss for 2018 was primarily due to higher general and administrative expenses as noted above as well as higher interest expense related to convertible promissory notes.

Results of Operations for the Years ended December 31, 2017 and 2016

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2017 were $738,527, compared to $1,376,063 for the same period in 2016, a decrease of $637,536, or 46%. Revenue resulted primarily from sales in Europe, Asia, and Asia/Pacific of our orthoPACE devices and related applicators and upfront distribution fee from our Brazilian distribution agreement with MundiMed. The decrease in revenue for 2017 is primarily due to a decrease in sales of orthoPACE devices in

Asia/Pacific and the European Community, as compared to the prior year, as well as lower sales of new and refurbished applicators.

Cost of revenues for the year ended December 31, 2017 were $241,970, compared to $565,129 for the same period in 2016. Gross profit as a percentage of revenues was 67% for the year ended December 31, 2017, compared to 59% for the same period in 2016. The increase in gross profit as a percentage of revenues in 2017 was primarily due to higher revenue for refurbishment license and upfront distribution fee which have little or no related cost, as compared to 2016. Gross profit as a percentage of revenues excluding refurbishment license and upfront distribution fee revenue decreased for the year ended December 31, 2017, compared to the same period in 2016 due to reduced pricing to customers for refurbishments and higher shipping costs.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2017 were $1,292,531, compared to $1,128,640 for the same period in 2016, an increase of $163,891, or 15%. Research and development expenses include the costs associated with the dermaPACE submission to the FDA, which incurred costs related to responses to questions from the FDA including the hiring of an independent consultant to perform software updates. In addition, a medical device and separate technical audit was performed related to our ISO certification in 2017.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2017 were $3,004,803, as compared to $2,673,773 for the same period in 2016, an increase of $331,030, or 12%. The increase in general and administrative expenses in 2017, as compared to 2016, was due to an increase in board of directors fees related to adding a member to the board, costs associated with symposium hosted in December 2017, increased costs associated with investor relations consultants, and increased non-cash stock based compensation related to stock option and stock warrants issued in 2017.

Depreciation and Amortization

Depreciation for the year ended December 31, 2017 was $24,069, compared to $19,858 for the same period in 2016, an increase of $4,211, or 21%. The increase was due to the full year of depreciation related to devices added to fixed assets in the prior year.

Amortization for the years ended December 31, 2017 and 2016 was $0 and $306,756, respectively. The decrease is due to the intangible assets being fully amortized as of December 31, 2016.

Other Income (Expense)

Other income (expense) was a net expense of $1,713,490 for the year ended December 31, 2017 as compared to a net expense of $3,122,541 for the same period in 2016, a decrease of $1,409,051 in the net expense. The net expense in 2017 included a non-cash loss of $568,729 for a valuation adjustment on outstanding warrants, as compared to a net expense in 2016 included a non-cash loss of $2,223,718 for a valuation adjustment on outstanding warrants and conversion of Series A Warrants. The is partially offset by increased interest expense, beneficial conversion discount and debt discount in 2017, as compared to 2016, mainly due to convertible promissory notes issued in the fourth quarter of 2017.

Provision for Income Taxes

At December 31, 2017, we had federal net operating loss carryforwards of $78,455,234 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

Net Loss

Net loss for the year ended December 31, 2017 was $5,537,936, or ($0.04) per basic and diluted share, compared to a net loss of $6,439,040, or ($0.06) per basic and diluted share, for the same period in 2016, a decrease in the net loss of $901,104, or 14%. The decrease in the net loss was primarily a result of decreased loss on warrant valuation that is partially offset by increase in operating expenses.

We anticipate that our operating losses will continue over the next few years as we prepare for the commercialization of the dermaPACE System for the treatment of diabetic foot ulcers in the United States but if we are able to successfully commercialize, market and distribute the dermaPACE System, then we hope to partially or completely offset these losses within the next few years.

Liquidity and Capital Resources

We expect to devote substantial resources for the commercialization of the dermaPACE System and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $9,570,056 for the nine months ended September 30, 2018 and $5,537,936 for the year ended December 31, 2017. These operating losses create uncertainty about our ability to continue as a going concern.

The continuation of our business is dependent upon raising additional capital during the fourth quarter of 2018 and the first quarter of 2019 to fund operations. Management expects the cash used in operations for the Company will be approximately $175,000 to $250,000 per month for 2018 as resources are devoted to the expansion of our international business, preparations for commercialization of the dermaPACE product including hiring of new employees and continued research and development of non-medical uses of our technology. Management's plans are to obtain additional capital in 2018 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

In addition, we may have potential liability for certain issuances of shares of Common Stock in possible violation of federal securities laws. The issuance of shares of Common Stock underlying certain of our warrants may have been in violation of the Section 5 of the Securities Act and the rules and regulations under the Securities Act. Eligible warrantholders have not filed a claim against the Company alleging a violation of the Section 5 of the Securities Act, but they could file such a claim in the future. If a violation of the Section 5 of the Securities Act did in fact occur, eligible warrantholders, which the Company estimates represents fewer than 10 warrantholders, would have a right to rescind their exercises of warrants and the Company may have to refund any cash amounts paid for such exercises, which could have a materially adverse effect on the Company's financial condition.

On December 29, 2017, the Company entered into a line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. On June 21, 2018, the Company made a payment of $144,500 on the line of credit. On June 26, 2018, the amount of the line of credit was increased by $280,500. The line of credit may be called for payment upon demand.

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder. On October 5, 2018 and October 23, 2018, the Company received $15,000 and $40,000, respectively, as an increase in the line of credit.

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. ("NFS") to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE System in the marketplace. This agreement provides for a lease line of up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company's accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company. As of February 27, 2018, we were in default of Master Equipment Lease due to the sale of

equipment purchased under the Master Lease Agreement to a third party and, as a result, the note is callable by NFS or NFS. could have notified the Company to assemble all equipment for pick up. The Master Equipment Lease was paid in full on June 27, 2018.

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

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

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

For the years ended December 31, 2017 and 2016, net cash used by operating activities was $1,528,971 and $3,199,453, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for the year ended December 31, 2017, as compared to the same period for 2016, of $1,670,482, or 52%, was primarily due to the increase in accounts receivable of $250,678 and in accounts payable and accrued expenses of $1,082,071. Net cash used by investing activities in 2017 was $0 as compared to net cash provided by investing activities in 2016 of $8,770 from the purchase of property and equipment. Net cash provided by financing activities for the year ended December 31, 2017 was $2,117,298, which primarily consisted of the net proceeds from convertible promissory notes of $1,384,232, proceeds from related party line of credit of $370,000, proceeds from advances from related parties of $310,000 and proceeds from warrant exercises of $93,066. Net cash provided by financing activities for the year ended December 31, 2016 was $3,207,771, which primarily consisted of the net proceeds from 2016 Public Offering of $1,596,855, 2016 Private Placement of $1,528,200, and proceeds from warrant exercises of $67,466. Cash and cash equivalents increased by $596,613 for the year ended December 31, 2017 and cash and cash equivalents decreased by $19,359 for the year

ended December 31, 2016.

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.

In August 2016, we entered into a lease agreement for the operations, production and research and development office for 7,500 square feet of space. Under the terms of the lease, we pay monthly rent of $10,844, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The term of the lease is 65 months.

We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantities of product component materials for our products through the development, clinical testing and commercialization phases. We have a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our devices.

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, Inc., we issued two notes to HealthTronics, Inc. for $2,000,000 each. The notes bear interest at 6% annually. Quarterly interest through June 30, 2010 was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal was due August 1, 2015. Accrued interest on the notes which matured in August 2015 totaled $1,372,743 at December 31, 2017 and 2016.

On June 15, 2015, we entered into an amendment (the “Note Amendment”) with HealthTronics, Inc. to amend certain provisions of the notes payable, related parties. The Note Amendment provides for the extension of the due date to January 31, 2017. In connection with the Note Amendment, we entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. The notes payable, related parties will bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. Events of Default under the notes payable, related parties have occurred and are continuing on account of the failure of SANUWAVE, Inc., a wholly owned subsidiary of the Company and the borrower under the notes payable, related parties, to make the required payments of interest which were due on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017, and December 31, 2017 (collectively, the “Defaults”). As a result of the Defaults, the notes payable, related parties have been accruing interest at the rate of 10% per annum since January 2, 2017 and continue to accrue interest at such rate. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company’s patents or other intellectual property rights.

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

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

In addition, the Company, in connection with the Second Amendment, issued to HealthTronics, Inc. on June 28, 2016, an additional 1,890,000 Class K Warrants to purchase shares of the Company’s Common Stock at an exercise price of $0.08 per share, subject to certain anti-dilution protection. The exercise price of the 3,310,000 Class K Warrants issued on June 15, 2015 was decreased to $0.08 per share.

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

In addition, the Company, in connection with the Third Amendment, issued to HealthTronics, Inc. on August 3, 2017, an additional 2,000,000 Class K Warrants to purchase shares of the Company’s Common Stock at an exercise price of $0.11 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one

share of Common Stock. The warrants vested upon issuance and expire after ten years.

Recently Issued Accounting Standards

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

In May 2014, the Financial Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASC 606), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASC 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASC 606 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. The standard was declared effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective method, which requires the standard to be applied to each prior period presented, or (ii) a modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to the opening retained earnings in the period of adoption. In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2018 instead of the previous effective date, which was the first quarter of fiscal 2017. This one year deferral was issued by the FASB in ASU 2015-14, Revenue from Contracts with Customers (Topic 606). The Company adopted the new standard on a modified retrospective basis as of January 1, 2018. The Company completed an assessment of customer contracts and concluded that the adoption of ASC 606 did not have a material impact on its condensed consolidated financial statements; therefore, no cumulative-effect adjustment was recorded on the adoption date. The disclosures related to revenue recognition have been significantly expanded under the standard, specifically around the quantitative and qualitative information about performance obligations and disaggregation of revenue. The expanded disclosure requirements are included in this Quarterly Report on Form 10-Q (see Notes 5 and 15).

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

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

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

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480): Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this ASU addresses the complexity and reporting burden associated with the accounting for freestanding and embedded instruments with down round features as liabilities subject to fair value measurement. Part

II of this ASU addresses the difficulty of navigating Topic 480. Part I of this ASU will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for an entity in an interim or annual period. Management is evaluating the requirements of this guidance and has not yet determined the impact of the pending adoption on the Company's financial position or results of operations.

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

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements ("ASU 2018-09"). These amendments provide clarifications and corrections to certain ASC subtopics including the following: Income Statement - Reporting Comprehensive Income – Overall (Topic 220-10), Debt - Modifications and Extinguishments (Topic 470-50), Distinguishing Liabilities from Equity – Overall (Topic 480-10), Compensation - Stock Compensation - Income Taxes (Topic 718-740), Business Combinations - Income Taxes (Topic 805-740), Derivatives and Hedging – Overall (Topic 815- 10), and Fair Value Measurement – Overall (Topic 820-10). The majority of the amendments in ASU 2018-09 will be effective in annual periods beginning after December 15, 2018. The Company is currently evaluating and assessing the impact this guidance will have on its condensed consolidated financial statements.

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

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

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

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

Because 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.

BUSINESS

Overview

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

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. In 2018, we have started marketing our dermaPACE System for sale in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific. Our lead product candidate for the global wound care market, dermaPACE, has received FDA approval 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 OssaTron, Evotron®, and orthoPACE® 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, for sterilizing food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

We were formed as a Nevada corporation in 2004.

Pulsed Acoustic Cellular Expression (PACE) Technology for Regenerative Medicine

Our PACE product candidates, including our lead product candidate, dermaPACE, deliver high-energy acoustic pressure waves in the shockwave spectrum to produce compressive and tensile stresses on cells and tissue structures. These mechanical stresses at the cellular level have been shown in pre-clinical work to promote angiogenic and positive inflammatory responses, and quickly initiate the healing cascade. This has been shown in pre-clinical work to result in microcirculatory improvement, including increased perfusion and blood vessel widening (arteriogenesis), the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE procedures trigger the initiation of an accelerated inflammatory response that speeds wounds into proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help reinitiate the body's own healing response. We believe that our PACE technology is well suited for various applications due to its activation of a broad spectrum of cellular events critical for the initiation and progression of healing.

High-energy, acoustic pressure shock waves are the primary component of our previously developed product, OssaTron, which was approved by the FDA and marketed in the United States for use in chronic plantar fasciitis of the foot in 2000 and for elbow tendonitis in 2003. Previously, acoustic pressure shock waves have been used safely at much higher energy and pulse levels in the lithotripsy procedure (breaking up kidney stones) by urologists for over 25 years and has reached the care status of “golden standard” for the treatment of kidney stones.

We research, design, manufacture, market and service our products worldwide and believe we have already demonstrated that our 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, Evotron and OssaTron devices in Europe and Asia.

We believe our experience from our preclinical research and the clinical use of our predecessor legacy devices in Europe and Asia, as well as our OssaTron device in the United States, demonstrates the safety, clinical utility and efficacy of these products. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications.

Currently, there are limited biological or mechanical therapies available to activate the healing and regeneration of tissue, bone and vascular structures. As baby boomers age, the incidence of their targeted diseases and musculoskeletal injuries and ailments will be far more prevalent. We believe that our pre-clinical and clinical studies suggest that our PACE technology will be effective in targeted applications. If successful, we anticipate that future clinical studies should lead to regulatory approval of our regenerative product candidates in the United States, Europe and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and noninvasive treatment options in wound healing, orthopedic injuries, plastic/cosmetic uses and cardiac procedures, improving the quality of life for millions of patients suffering from injuries or deterioration of tissue, bones and vascular structures.

dermaPACE Our Lead Product Candidate

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

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

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

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

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm2 and 16cm2, inclusive. Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 Day 0), the first treatment was applied (either dermaPACE or Sham Control application). Applications with either dermaPACE or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

A total of 336 patients were enrolled in the dermaPACE studies at 37 sites. The patients in the studies were followed for a total of 24 weeks. The studies primary endpoint, wound closure, was defined as “successful” if the skin was 100% re-epithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits.

A summary of the key study findings were as follows:

Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study (p=0.320). There were 39 out of 172 (22.67%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 30 out of 164 (18.29%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, and in conjunction with the FDA agreement to analyze the efficacy analysis carried over the full 24 weeks of the study, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 61 (35.47%) dermaPACE subjects achieving complete wound closure compared with 40 (24.39%) of sham-control subjects (p=0.027). At the 24 week endpoint, the rate of wound closure in the dermaPACE® cohort was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023.

Within 6 weeks following the initial dermaPACE treatment, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive sham-control ($p<0.05$).

The proportion of patients with wound closure indicate a statistically significant difference between the dermaPACE and the control group in the proportion of subjects with the target-ulcer not closed over the course of the study (p-value=0.0346). Approximately 25% of dermaPACE® subjects reached wound closure per the study definition by day 84 (week 12). The same percentage in the control group (25%) did not reach wound closure until day 112 (week 16). These data indicate that in addition to the proportion of subjects reaching wound closure being higher in the dermaPACE® group, subjects are also reaching wound closure at a faster rate when dermaPACE is applied.

dermaPACE demonstrated superior results in the prevention of wound expansion (≥ 10% increase in wound size), when compared to the control, over the course of the study at 12 weeks (18.0% versus 31.1%; p=0.005, respectively).

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

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

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

Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which

suggests that a second course of treatment, if needed, is a clinically viable option.

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

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

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

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

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Our FDA approval in the United States for our lead product candidate, dermaPACE, is the first step in providing an option to a currently unmet need in the treatment of diabetic foot ulcers. Diabetes is common, disabling and deadly. In the United States, diabetes has reached epidemic proportions. Based on our research, foot ulcerations are one of the leading causes of hospitalization in diabetic patients and lead to billions of dollars in health care expenditures annually. According to a 2015 report by the Centers for Disease Control and Prevention, approximately 30.3 million people (diagnosed and undiagnosed), roughly 9.4% of the United States population, have diabetes and 1.5 million new cases of diabetes were diagnosed in people aged 18 years or older in 2015. According to the same study, approximately 25% of diabetics will develop a diabetic foot ulceration ("DFU") during their lifetime. Foot ulcers are a significant complication of diabetes mellitus and often precede lower-extremity amputation. The most frequent underlying etiologies are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease. Over 50% of DFUs will become infected, resulting in high rates of hospitalization, increased morbidity and potential lower extremity amputation. Diabetic foot infections ("DFI") are one of the most common diabetes related cause of hospitalization in the United States, accounting for 20% of all hospital admissions. Readmission rates for DFI patients are approximately 40% and nearly one in six patients die within 1 year of their infection. In a large prospective study of patients with DFU, the presence of infection increased the risk of a minor amputation by 50% compared to ulcer patients without infection. DFUs account for more than half of the non-traumatic lower-extremity amputations in the world. The Advanced Medical Technology Association ("AdvaMed") estimates that chronic leg wounds (ulcers) account for the loss of many workdays per year, at a cost of approximately $20.8 billion in lost productivity. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need globally, yet in short supply. According to the International Diabetes Federation, 1 in 11 adults has diabetes (approximately 425 million people) and 12% of global health expenditure is spent on diabetes (approximately $727 billion).

A majority of challenging wounds are non-healing chronic wounds and in addition, chronic diabetic foot ulcers and pressure ulcers are often slow-to-heal wounds, which often fail to heal for many months, and sometimes, for several years. These wounds often involve physiologic, complex and multiple complications such as reduced blood supply, compromised lymphatic systems or immune deficiencies that interfere with the body's normal wound healing processes. These wounds often develop due to a patients impaired vascular and tissue repair capabilities. Wounds that are difficult to treat do not always respond to traditional therapies, which include hydrocolloids, hydrogels and alginates, among other treatments. We believe that physicians and hospitals need a therapy that addresses the special needs of these chronic wounds with high levels of both clinical and cost effectiveness.

We believe we are developing a safe and advanced technology in the wound healing and tissue regeneration market with PACE. dermaPACE is noninvasive and does not require anesthesia, making it a cost-effective, time-efficient and painless approach to wound care. Physicians and nurses look for therapies that can accelerate the healing process and overcome the obstacles of patients compromised conditions, and prefer therapies that are easy to administer. In addition, since many of these patients are not confined to bed, healthcare providers want therapies that are minimally disruptive to the patients or the caregivers daily routines. dermaPACEs noninvasive treatments are designed to elicit the body's own healing response and, followed by simple standard of care dressing changes, are designed to allow for

limited disruption to the patients normal lives and have no effect on mobility while their wounds heal.

Developing Product Opportunities - Orthopedic

We launched the orthoPACE device in Europe, which is intended for use in orthopedic, trauma and sports medicine indications, following CE Marking approval in 2010. The device features four types of applicators including a unique applicator that is less painful for some indications and may reduce or completely eliminate anesthesia for some patients. In the orthopedic setting, the orthoPACE is being used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs. In 2013, we obtained approval from South Koreas Ministry of Food and Drug Safety to market orthoPACE in that country.

We believe there are significant opportunities in the worldwide orthopedic market, driven by aging baby boomers and their desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

We have experience in the sports medicine field (which generally refers to the non-surgical and surgical management of cartilage, ligament and tendon injuries) through our legacy devices, OssaTron and Evotron. Common examples of these injuries include extremity joint pain, torn rotator cuffs (shoulder), tennis elbow, Achilles tendon tears and torn meniscus cartilage in the knee. Injuries to these structures are very difficult to treat because the body has a limited natural ability to regenerate these tissues. Cartilage, ligament and tendons seldom return to a pre-injury state of function. Due to a lack of therapies that can activate healing and regenerate these tissues, many of these injuries will result in a degree of permanent impairment and chronic pain. Prior investigations and pre-clinical work indicate that PACE can activate various cell types and may be an important adjunct to the management of sports medicine injuries.

Trauma injuries are acute and result from any physical damage to the body caused by violence or accident or fracture. Surgical treatment of traumatic fractures often involves fixation with metallic plates, screws and rods (internal fixation) and include off-loading to prevent motion, permitting the body to initiate a healing response. In the United States, six million traumatic fractures are treated each year, and over one million internal fixation procedures are performed annually. The prevalence of non-union among these fractures is between 2.5% and 10.0% depending on the fracture type and risk factors such as diabetes and smoking history or other systemic diseases. At the time of surgery, adjunctive agents (such as autograft, cadaver bone and synthetic filling materials) are often implanted along with internal fixation to fill bony gaps or facilitate the healing process to avoid delayed union or non-union (incomplete fracture healing) results. Both pre-clinical and clinical investigations have shown positive results, suggesting our technology could potentially be developed as an adjunct to these surgeries or primary treatment protocol for delayed or non-union events.

Non-Medical Uses For Our Shockwave Technology

We believe there are significant license/partnership opportunities for our shockwave technology in non-medical uses, including in the energy, water, food and industrial markets.

Due to their powerful pressure gradients and localized cavitational effects, we believe that high-energy, acoustic pressure shock waves can be used to clean, in an energy efficient manner, contaminated fluids from impurities, bacteria, viruses and other harmful micro-organisms, which provides opportunities for our technology in cleaning industrial and domestic/municipal waters. Based on the same principles of action of the acoustic pressure shock waves against bacteria, viruses and harmful micro-organisms, we believe our technology can be applied for cleaning or sterilization of various foods such as milk, natural juices and meats.

In the energy sector, we believe that the acoustic pressure shock waves can be used to improve oil recovery (IOR), as a supplement to or in conjunction with existing fracking technology, which utilizes high pressurized water/gases to crack the rocks that trapped oil in the underground reservoir. Through the use of our high-energy, acoustic pressure shock waves the efficiency can be improved and in the same time the environmental impact of the fracking process can be reduced. Furthermore, we believe our technology can be used for enhanced oil recovery (EOR) based on the changes in oil flow characteristics resulting from acoustic pressure shock wave stimulation, as a tertiary method of oil recovery from older oil fields.

Additionally, we demonstrated through two studies performed at Montana State University that high-energy, acoustic pressure shock waves are disrupting biofilms and thus can be used for surface cleaning or to unclog pipes in the energy industry (shore or off-shore installations), food industry and water management industry, which will reduce or

eliminate down times with significant financial benefits for maintenance of existing infrastructure.

Market Trends

We are focused on the development of regenerative medicine products that have the potential to address substantial unmet clinical needs across broad market indications. We believe there are limited therapeutic treatments currently available that directly and reproducibly activate healing processes in the areas in which we are focusing, particularly for wound care and repair of certain types of musculoskeletal conditions.

According to AdvaMed and Centers for Medicare & Medicaid Services data and our internal projections, the United States advanced wound healing market for the dermaPACE is estimated at $20 billion, which includes diabetic foot ulcers, pressure sores, burns and traumatic wounds, and chronic mixed leg ulcers. We also believe there are significant opportunities in the worldwide orthopedic and spine markets, driven by aging baby boomers and their desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

With the success of negative pressure wound therapy devices in the wound care market over the last decade and the recognition of the global epidemic associated with certain types of wounds, as well as deteriorating musculoskeletal conditions attributed to various disease states such as obesity, diabetes and ischemia due to vascular and heart disease, as well as sports injuries, we believe that Medicare and private insurers have become aware of the costs and expenditures associated with the adjunctive therapies being utilized for wound healing and orthopedic conditions with limited efficacies in full skin closure, or bone and tissue regeneration. We believe the wound healing and orthopedic markets are undergoing a transition, and market participants are interested in biological response activating devices that are applied noninvasively and seek to activate the body's own capabilities for regeneration of tissue at injury sites in a cost-effective manner.

Strategy

Our primary objective is to be a leader in the development and commercialization of our acoustic pressure shock wave technology for regenerative medicine and other applications. Our initial focus is regenerative medicine utilizing noninvasive (extracorporeal), acoustic pressure shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of skin, musculoskeletal tissue and vascular structures. Our lead regenerative product in the United States is the dermaPACE device for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies and cleared by the 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 cardiovascular conditions.

Our immediate goal for our regenerative medicine technology involves leveraging the knowledge we gained from our existing human heel and elbow indications to enter the advanced wound care market with innovative treatments.

The key elements of our strategy include the following:

Commercialize and support the domestic distribution of our dermaPACE device to treat diabetic foot ulcers.

We initially focused on obtaining FDA approval in the United States for our lead product candidate, dermaPACE, for the treatment of diabetic foot ulcers, which we believe represents a large, unmet need. On December 28, 2017, the FDA notified the Company to permit the marketing of the dermaPACE System for the treatment of diabetic foot ulcers in the United States. We plan to begin the commercialization of dermaPACE in the United States in 2018 through strategic partnerships or commercialize the product ourselves. For example, in February 2018, we entered into an agreement with Premier Shockwave Wound Care, Inc. ("PSWC") and Premier Shockwave, Inc. ("PS") for the purchase by PSWC and PS of dermaPACE Systems and related equipment sold by us, including a minimum purchase of 100 units over 3 years, and granting PSWC and PS limited but exclusive distribution rights to provide dermaPACE Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to us.

Develop and commercialize our noninvasive biological response activating devices in the regenerative medicine area for the treatment of skin, musculoskeletal tissue and vascular structures.

We intend to use our proprietary technologies and know-how in the use of high-energy, acoustic pressure shock waves to address unmet medical needs in wound care, orthopedic, plastic/cosmetic and cardiac indications, possibly through potential license and/or partnership arrangements.

License and seek partnership opportunities for our non-medical acoustic pressure shock wave technology platform, know-how and extensive patent portfolio.

We intend to use our acoustic pressure shock wave technology and know-how for non-medical uses, including energy, food, water cleaning and other industrial markets, through license/partnership opportunities.

Support the global distribution of our products.

Our portfolio of products, the dermaPACE and orthoPACE, are CE Marked and sold through select distributors in certain countries in Europe, Canada, Asia and Asia/Pacific. Our revenues will continue from sales of the devices and related applicators in these markets. We intend to continue to add additional distribution partners in the Americas, Middle East, Africa, Europe and Asia/Pacific.

Scientific Advisors

We have established a network of advisors that brings expertise in wound healing, orthopedics, cosmetics, clinical and scientific research, and FDA experience. We consult our scientific advisors on an as-needed basis on clinical and pre-clinical study design, product development, and clinical indications.

We pay consulting fees to certain members of our scientific advisory board for the services they provide to us, in addition to reimbursing them for incurred expenses. The amounts vary depending on the nature of the services. We paid our advisors aggregate consulting fees through the issuance of stock options in 2017 and 2016 and recorded stock-based compensation expense of $39,127 and $30,421 for the years ended December 31, 2017 and 2016, respectively.

Sales, Marketing and Distribution

Following FDA approval in December 2017, we intend to seek a development and/or commercialization partnership, or to commercialize a product ourselves. Outside the United States, we retain distributors to represent our products in selective international markets. These distributors have been selected based on their existing business relationships and the ability of their sales force and distribution capabilities to effectively penetrate the market with our PACE product line. We rely on these distributors to manage physical distribution, customer service and billing services for our international customers. Five distributors accounted for 7%, 24%, 20%, 9% and 27% of revenues for the nine months ended September 30, 2018, and 0%, 60%, 0%, 0% and 6% of accounts receivable at September 30, 2018. Three distributors accounted for 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017.

We have developed a network of suppliers, manufacturers and contract service providers to provide sufficient quantities of our products.

We are party to a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our products. Our generator boxes are manufactured in accordance with applicable quality standards (EN ISO 13485) and applicable industry and regulatory standards. We produce the applicators and applicator kits for our products. In addition, we program and load software and perform the final product testing and certifications internally for all of our devices.

Our facility in Suwanee, Georgia consists of 7,500 square feet and provides office, research and development, quality control, production and warehouse space. It is a FDA registered facility and is ISO 13485 certified (for meeting the requirements for a comprehensive management system for the design and manufacture of medical devices).

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing upon our proprietary rights. We seek to protect our proprietary position by, among other

methods, filing United States and selected foreign patent applications and United States and selected foreign trademark applications related to our proprietary technology, inventions, products, and improvements that are important to the development of our business. Effective trademark, service mark, copyright, patent, and trade secret protection may not be available in every country in which our products are made available. The protection of our intellectual property may require the expenditure of significant financial and managerial resources.

Patents

We consider the protection afforded by patents important to our business. We intend to seek and maintain patent protection in the United States and select foreign countries where deemed appropriate for products that we develop. There are no assurances that any patents will result from our patent applications, or that any patents that may be issued will protect our intellectual property, or that any issued patents or pending applications will not be successfully challenged, including as to ownership and/or validity, by third parties. In addition, if we do not avoid infringement of the intellectual property rights of others, we may have to seek a license to sell our products, defend an infringement action or challenge the validity of intellectual property in court. Any current or future challenges to our patent rights, or challenges by us to the patent rights of others, could be expensive and time consuming.

We derive our patent rights, including as to both issued patents and “patent pending” applications, from three sources: (1) assignee of patent rights in technology we developed; (2) assignee of patent rights purchased from HealthTronics, Inc. (“HealthTronics”); and (3) as licensee of certain patent rights assigned to HealthTronics. In August 2005, we purchased a significant portion of our current patents and patent applications from HealthTronics, to whom we granted back perpetual and royalty-free field-of-use license rights in the purchased patent portfolio primarily for urological uses. We believe that our owned and licensed patent rights provide a competitive advantage with respect to others that might seek to utilize certain of our apparatuses and methods incorporating extracorporeal acoustic pressure shock wave technologies that we have patented; however, we do not hold patent rights that cover all of our products, product components, or methods that utilize our products. We also have not conducted a competitive analysis or valuation with respect to our issued and pending patent portfolio in relation to our current products and/or competitor products.

We are the assignee of twenty-eight issued United States patents and eighteen issued foreign patents, which on average have remaining useful lives of ten years with the longest useful life extending to 2036. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations, piezoelectric fiber shock wave devices, chemical components for shock wave generation, reflector geometries, medical systems general construction, and detachable therapy heads with data storage devices. Our United States patents also include patent claims directed to methods of using acoustic pressure shock waves, including devices such as our products, to treat ischemic conditions, spinal cord scar tissue and spinal injuries, bone fractures and osteoporosis, blood sterilization, stem cell stimulation, tissue cleaning, and, within particular treatment parameters, diabetic foot ulcers and pressure sores. While such patented method claims may provide patent protection against certain indirect infringing promotion and sales activities of competing manufacturers and distributors, certain medical methods performed by medical practitioners or related health care entities may be subject to exemption from potential infringement claims under 35 U.S.C. § 287(c) and, therefore, may limit enforcement of claims of our method patents as compared to device and non-medical method patents.

We also currently maintain eleven United States non-provisional patent applications and seven foreign patent applications. Our patent-pending rights include inventions directed to certain shock wave devices and systems, ancillary products, and components for acoustic pressure shock wave treatment devices, and various methods of using acoustic pressure shock waves. Such patent-pending methods include, for example, using acoustic pressure shock waves to treat soft tissue disorders, bones, joints, wounds, skin, blood vessels and circulatory disorders, lymphatic disorders, cardiac tissue, fat and cellulite, cancer, blood and fluids sterilization, to destroy pathogens, to process fluids, meat and dairy products, to destroy blood vessels occlusions and plaques, and to perform personalized medical treatments. All of our United States and foreign pending applications either have yet to be examined or require response to an examiners office action rejections and, therefore, remain subject to further prosecution, the possibility of further rejections and appeals, and/or the possibility we may elect to abandon prosecution, without assurance that a patent may issue from any pending application.

Under our license to HealthTronics, we reserve exclusive rights in our purchased portfolio as to orthopedic, tendonopathy, skin wounds, cardiac, dental, neural medical conditions and to all conditions in animals (Ortho Field). HealthTronics receives field-exclusive and sublicensable rights under the purchased portfolio as to (1) certain HealthTronics lithotripsy devices in all fields other than the Ortho Field, and (2) all products in the treatment of renal, ureteral, gall stones and other urological conditions (Litho Field). HealthTronics also receives non-exclusive and non-sublicensable rights in the purchased portfolio as to any products in all fields other than the Ortho Field and Litho Field.

Pursuant to mutual amendment and other assignment-back rights under the patent license agreement with HealthTronics, we are also a licensee of certain patents and patent applications that have been assigned to HealthTronics. We received a perpetual, non-exclusive and royalty-free license to nine issued foreign patents. Our non-exclusive license is subject to HealthTronics sole discretion to further maintain any of the patents and pending applications assigned back to HealthTronics.

As part of the sale of the veterinary business in June 2009, we have also granted certain exclusive and non-exclusive patent license rights to Pulse Veterinary Technologies, LLC for most of our patent portfolio issued before 2009 to utilize acoustic pressure shock wave technologies in the field of non-human mammals.

Given our international patent portfolio, there are growing risks of challenges to our existing and future patent rights. Such challenges may result in invalidation or modification of some or all of our patent rights in a particular patent territory and reduce our competitive advantage with respect to third party products and services. Such challenges may also require the expenditure of significant financial and managerial resources.

If we become involved in future litigation or any other adverse intellectual property proceeding, for example, as a result of an alleged infringement, or a third party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, including treble damages, invalidation of our intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business, financial condition and results of operation. In addition, any claims relating to the infringement of third party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation or lengthy governmental proceedings and could divert management's attention and resources and require us to enter into royalty or license agreements which are not advantageous, if available at all.

Trademarks

Since other products on the market compete with our products, we believe that our product brand names are an important factor in establishing and maintaining brand recognition.

We have the following trademark registrations: SANUWAVE® (United States, European Community, Canada, Japan, Switzerland, Taiwan and under the Madrid Protocol), dermaPACE® (United States, European Community, Japan, South Korea, Switzerland, Taiwan, Canada and under the Madrid Protocol), angioPACE® (Australia, European Community and Switzerland), PACE® (Pulsed Acoustic Cellular Expression) (United States, European Community, China, Hong Kong, Singapore, Switzerland, Taiwan, and Canada), orthoPACE® (United States and European Community), DAP® (Diffused Acoustic Pressure) (United States and European Community) and Profile™ (United States, European Community and Switzerland).

We also maintain trademark registrations for: OssaTron® (United States and Germany), evoPACE® (Australia, European Community and Switzerland), Evotron® (Germany and Switzerland), Evotrode® (Germany and Switzerland), Orthotripsy® (United States). We are phasing out the Reflectron® (Germany and Switzerland) and Reflectrode® (Germany and Switzerland) trademarks due to the fact that these two products are no longer available for sale in any market.

Potential Intellectual Property Issues

Although we believe that the patents and patent applications, including those that we license, provide a competitive advantage, the patent positions of biotechnology and medical device companies are highly complex and uncertain. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Our success will depend in part on us not infringing on patents issued to others, including our competitors and potential competitors, as well as our ability to enforce our patent rights. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products and product candidates, or to obtain and use information that we regard as proprietary. In enforcement proceedings in Switzerland, we assisted HealthTronics as an informer of misappropriation by a Swiss company called SwiTech and related third parties of intellectual property rights in legacy proprietary software and devices relating to assets we purchased from HealthTronics in August 2005. As a result of this action, SwiTech was forced into bankruptcy. We also pursued the alleged misappropriation by another Swiss company called SwiTalis and related third parties of intellectual property rights in legacy proprietary software and devices relating to assets we purchased from HealthTronics in August 2005. In 2016, SwiTalis claimed copyright rights on the High Voltage Modules that were used in our devices and the old line of Pulse Vet devices during the manufacturing process at Swisstronics in Switzerland. At this time, however, no such court action against Swisstronics is pending in Switzerland and we believe that it is unlikely that SwiTalis will pursue their earlier allegations against Swisstronics and, indirectly, us. In 2017, we abandoned our action against SwiTalis. There can be no assurance, however, that future claims or lawsuits against us may not be brought, and such present or future actions against violations of our intellectual property rights may result in us incurring material expense and divert the attention of management.

Third parties that license our proprietary rights, such as trademarks, patented technology or copyrighted material, may also take actions that diminish the value of our proprietary rights or reputation. In addition, the steps we take to protect our proprietary rights may not be adequate and third parties may infringe or misappropriate our copyrights, trademarks, trade dress, patents, and similar proprietary rights.

We collaborate with other persons and entities on research, development, and commercialization activities and expect to do so in the future. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, researchers, licensors, licensees and consultants. In addition, other parties may circumvent any proprietary protection that we do have. As a result, we may not be able to maintain our proprietary position.

Competition

We believe the advanced wound care market can benefit from our technology which up-regulates the biological factors that promote wound healing. Current medical technologies developed by Acelity (formerly Kinetic Concepts, Inc.), Organogenesis, Inc., Smith &Nephew plc, Derma Sciences, Inc., MiMedx Group, Inc., Osiris Therapeutics, Inc., Molnlycke Health Care, and Systagenix Wound Management (US), Inc. (now owned by Acelity) manage wounds, but, in our opinion, do not provide the value proposition to the patients and care givers like our PACE technology has the potential to do. The leading medical device serving this market is the Vacuum Assisted Closure (“V.A.C.”) System marketed by KCI. The V.A.C. is a negative pressure wound therapy device that applies suction to debride and manage wounds.

There are also several companies that market extracorporeal shock wave device products targeting lithotripsy and orthopedic markets, including Dornier MedTech, Storz Medical AG, Electro Medical Systems (EMS) S.A., CellSonic Medical and Tissue Regeneration Technologies, LLC, and could ultimately pursue the wound care market. Nevertheless, we believe that dermaPACE has a competitive advantage over all of these existing technologies by achieving wound closure by means of a minimally invasive process through innate biological response to PACE.

Developing and commercializing new products is highly competitive. The market is characterized by extensive research and clinical efforts and rapid technological change. We face intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major pharmaceutical companies. We may be unable to respond to technological advances through the development and introduction of new products. Most of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources. These competitors may also be in the process of seeking FDA or other regulatory approvals, or patent protection, for new products. Our competitors may commercialize new products in advance of our products. Our products also face competition from numerous existing products and procedures, which currently are considered part of the standard of care. In order to compete effectively, our products will have to achieve widespread market acceptance.

Regulatory Matters

FDA Regulation

Each of our products must be approved or cleared by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our product candidates are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products.

In the United States, the FDA subjects medical products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products, and we may be criminally prosecuted. Failure to comply with the law could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension or withdrawal of product approval, injunctions, or criminal prosecution.

The FDA has determined that our technology and product candidates constitute “medical devices.” The FDA determines what center or centers within the FDA will review the product and its indication for use, and also determines under what legal authority the product will be reviewed. For the current indications, our products are being reviewed by the Center for Devices and Radiological Health. However, we cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case the governmental review requirements could vary in some respects.

FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy:

Class I: general controls, such as labeling and adherence to quality system regulations;

Class II: special controls, pre-market notification (510(k)), specific controls such as performance standards, patient registries, and post market surveillance, and additional controls such as labeling and adherence to quality system regulations; and

Class III: special controls and approval of a pre-market approval (PMA) application.

Each of our product candidates require FDA authorization prior to marketing, by means of either a 510(k) clearance or a PMA approval.

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device, has the same intended use, and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than does a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product modification that could significantly affect thesafety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then a company must submit and the FDA must approve a PMA before marketing can begin.

In the past, the 510(k) pathway for product marketing required only the proof of significant equivalence in technology for a given indication with a previously cleared device. Currently, there has been a trend of the FDA requiring additional clinical work to prove efficacy in addition to technological equivalence. Thus, no matter which regulatory pathway we may take in the future towards marketing products in the United States, we will be required to provide clinical proof of device effectiveness.

Within the past few years, the FDA has released guidelines for the FDAs reviewers to use during a products submission review process. This guidance provides the FDA reviewers with a uniform method of evaluating the benefits verses the risks of a device when used for a proposed specific indication. Such a benefit/risk evaluation is very useful when applied to a novel device or to a novel indication and provides the FDA with a consistent tool to document their decision process. While intended as a guide for internal FDA use, the public availability of this

guidance allows medical device manufacturers to use the review matrix to develop sound scientific and clinical backup to support proposed clinical claims and to help guide the FDA, through the decision process, to look at the relevant data. We intend to use this benefit/risk tool in our FDA submissions.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturers facilities for compliance with Quality System Regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances where the FDA has not. If the FDA finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

During the review of either a PMA application or 510(k) submission, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. We cannot be sure that our product candidates will be approved or cleared in a timely fashion or at all. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

Obtaining medical device clearance, approval, or licensing in the United States or abroad can be an expensive process. The fees for submitting an original PMA to the FDA for consideration of device approval are substantial. Fees for supplement PMAs are less costly but still can be substantial. International fee structures vary from minimal to substantial, depending on the country. In addition, we are subject to annual establishment registration fees in the United States and abroad. Device licenses require periodic renewal with associated fees as well. In the United States, there is an annual requirement for submitting device reports for Class III/PMA devices, along with an associated fee. Currently, we are registered as a Small Business Manufacturer with the FDA and as such are subject to reduced fees. If, in the future, our revenues exceed a certain annual threshold limit, we may not qualify for the Small Business Manufacturer reduced fee amounts and will be required to pay full fee amounts.

Clinical Trials of Medical Devices

One or more clinical trials are almost always required to support a PMA application and more recently are becoming necessary to support a 510(k) submission. Clinical studies of unapproved or un-cleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board (IRB) has approved the study.

During the study, the sponsor must comply with the FDAs IDE requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. We, the FDA, or the IRB at each institution at which a clinical trial is being conducted, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

Post-Approval Regulation of Medical Devices

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

the FDA Quality Systems Regulation (QSR), which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;

labeling and claims regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling;

the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experiences associated with use of the product; and

post market surveillance, including documentation of clinical experience and also follow-on, confirmatory studies.

We continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories.

International sales of medical devices manufactured in the United States that are not approved or cleared by the FDA are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Exported devices may also fall under the jurisdiction of the United States Department of Commerce/Bureau of Industry and Security and compliance with export regulations may be required for certain countries.

Manufacturing cGMP Requirements

Manufacturers of medical devices are required to comply with FDA manufacturing requirements contained in the FDAs current Good Manufacturing Practices (cGMP) set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-PMA approval inspection before we can use it. We and some of our third party service providers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

The primary regulatory environment in Europe is the European Union, which consists of 28 member states encompassing most of the major countries in Europe. In the European Union, the European Medicines Agency (EMA) and the European Union Commission have determined that dermaPACE, orthoPACE, OssaTron and Evotron will be regulated as medical device products. These devices have been determined to be Class IIb devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area.

The primary regulatory body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have an ISO 13485 certification, as well as meet additional requirements of Canadian laws. We currently maintain this certification. We maintain a device license for dermaPACE with Health Canada for the indication of “devices for application of shock waves (pulsed acoustic waves) on acute and chronic defects of the skin and subcutaneous soft tissue”.

The primary regulatory bodies and paths in Asia and Australia are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to current good manufacturing practice (cGMP), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with cGMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing

procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

United States Anti-Kickback and False Claims Laws

In the United States, there are Federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in Federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. Other provisions of Federal and state laws provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, certain states have implemented regulations requiring medical device and pharmaceutical companies to report all gifts and payments over $50 to medical practitioners. This does not apply to instances involving clinical trials. Although we intend to structure our future business relationships with clinical investigators and purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by Federal or state enforcement officials under these laws.

Third Party Reimbursement

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers compensation plans. These third party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been approved or cleared by the FDA for commercial distribution, we may find limited demand for the device until adequate reimbursement has been obtained from governmental and private third party payers.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third party payers, that an adequate level of reimbursement will be available or that the third party payers reimbursement policies will not adversely affect our ability to sell our products profitably.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use products, including ours.

One of the components in the reimbursement decision by most private insurers and governmental payers, including the Centers for Medicare & Medicaid Services, which administers Medicare, is the assignment of a billing code. Billing codes are used to identify the procedures performed when providers submit claims to third party payers for reimbursement for medical services. They also generally form the basis for payment amounts. We will seek new billing codes for the wound care indications of our products as part of our efforts to commercialize such products.

The initial phase of establishing a professional billing code for a medical service typically includes applying for a CPT Category III code for both hospital and in-office procedures. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as American Medical Association (AMA) CPT Editorial Panel review. A new CPT Category III code will be assigned if the AMA CPT Editorial Panel committee deems it meets the applicable criteria and is appropriate. In 2018, we applied for two, new CPT Category III codes for extracorporeal shock wave therapy (ESWT) in wound healing. It is anticipated these codes will be published by AMA/CPT for use beginning in 2020.

The secondary phase in the CPT billing code process includes the establishment of a permanent CPT Category I code in which relative value is analyzed and established by the AMA. The approval of this code, is based on, among other criteria, widespread usage and established clinical efficacy of the medical service.

There are also billing codes that facilities, rather than health care professionals, utilize for the reimbursement of operating costs for a particular medical service. For the hospital outpatient setting, the Centers for Medicare & Medicaid Services automatically classified the new ESWT wound healing CPT Category III codes into interim APC groups. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment.

We believe that the overall escalating costs of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. In addition, recent healthcare reform measures, as well as legislative and regulatory initiatives at the Federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third party payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

Confidentiality and Security of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), contains provisions that protect individually identifiable health information from unauthorized use or disclosure by covered entities and their business associates. The Office for Civil Rights of HHS, the agency responsible for enforcing HIPAA, has published regulations to address the privacy (the “Privacy Rule”) and security (the “Security Rule”) of protected health information (“PHI”). HIPAA also requires that all providers who transmit claims for health care goods or services electronically utilize standard transaction and data sets and to standardize national provider identification codes. In addition, the American Recovery and Reinvestment Act (“ARRA”) enacted the HITECH Act, which extends the scope of HIPAA to permit enforcement against business associates for a violation, establishes new requirements to notify the Office for Civil Rights of HHS of a breach of HIPAA, and allows the Attorneys General of the states to bring actions to enforce violations of HIPAA. Rules implementing various aspects of HIPAA are continuing to be promulgated.

We anticipate that, as we expand our dermaPACE business, we will in the future be a covered entity under HIPAA. We intend to adopt policies and procedures to comply with the Privacy Rule, the Security Rule and the HIPAA statute as such regulations become applicable to our business and as such regulations are in effect at such time.

In addition to the HIPAA Privacy Rule and Security Rule described above, we may become subject to state laws regarding the handling and disclosure of patient records and patient health information. These laws vary widely. Penalties for violation include sanctions against a laboratory’s licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against us for a violation of a state’s privacy laws. We intend to adopt policies and procedures to ensure material compliance with state laws regarding the confidentiality of health information as such laws become applicable to us and to monitor and comply with new or changing state laws on an ongoing basis.

Environmental and Occupational Safety and Health Regulations

Our operations are subject to extensive Federal, state, provincial and municipal environmental statutes, regulations and policies, including those promulgated by the Occupational Safety and Health Administration, the United States Environmental Protection Agency, Environment Canada, Alberta Environment, the Department of Health Services, and the Air Quality Management District, that govern activities and operations that may have adverse environmental effects such as discharges into air and water, as well as handling and disposal practices for solid and hazardous wastes. Some of these statutes and regulations impose strict liability for the costs of cleaning up, and for damages resulting from, sites of spills, disposals, or other releases of contaminants, hazardous substances and other materials and for the

investigation and remediation of environmental contamination at properties leased or operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. In addition, we may be subject to claims and lawsuits brought by private parties seeking damages and other remedies with respect to similar matters. We have not to date needed to make material expenditures to comply with current environmental statutes, regulations and policies. However, we cannot predict the impact and costs those possible future statutes, regulations and policies will have on our business.

Research and Development

For the years ended December 31, 2017 and 2016, we spent $1,292,531 and $1,128,640, respectively, on research and development activities which consists of fixes to the dermaPACE device software per FDA request, responses to FDA questions and research costs by partnering universities for non-medical uses of the PACE technology.

Employees

As of December 3, 2018, we had a total of thirteen employees in the United States. Of these, four were engaged in research and development which includes clinical, regulatory and quality. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

Properties

Our operations, production and research and development office is in a leased facility in Suwanee, Georgia, consisting of 7,500 square feet of space. Under the terms of the lease, we pay monthly rent of $10,844, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The term of the lease is 65 months.

Legal Proceedings

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

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

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

MANAGEMENT, EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE

Below are the names and certain information regarding the Company's executive officers and directors.

Name	Age	Position Held
Kevin A. Richardson, II	50	Director, Chairman and Chief Executive Officer
Lisa E. Sundstrom	48	Chief Financial Officer
Shri P. Parikh	46	President, Healthcare
Peter Stegagno	58	Chief Operating Officer
Iulian Cioanta, PhD	56	Chief Science and Technology Officer
John F. Nemelka	53	Director
Alan L. Rubino	64	Director
A. Michael Stolarski	48	Director
Maj-Britt Kaltoft	54	Director

Kevin A. Richardson II joined the Company as chairman of the board of directors in October of 2009 and joined SANUWAVE, Inc. as chairman of the board of directors in August of 2005. In November 2012, upon the resignation of the Company's former President and Chief Executive Officer, Christopher M. Cashman, Mr. Richardson assumed the role of Active Chief Executive Officer, in addition to remaining Chairman of the Board, through the hiring of Mr. Chiarelli in February 2013. In April 2014, Mr. Richardson assumed the role of Co-Chief Executive Officer. When Mr. Chiarelli departed the Company in 2014, Mr. Richardson again assumed the role as Acting Chief Executive Officer. On November 30, 2018, Mr. Richardson was hired to serve as Chief Executive Officer of the Company. Mr. Richardson brings to our board of directors a broad array of financial knowledge for healthcare and other industries. Since 2004, Mr. Richardson served as managing partner of Prides Capital LLC, an investment management firm, until its liquidation in September 2015. Mr. Richardson graduated from Babson College with a BS in Finance and Investments and earned an MBA in Finance from the University of North Carolina.

Lisa E. Sundstrom joined the Company as Controller in October of 2006, and in August of 2015, assumed the responsibilities of Interim Chief Financial Officer. In December 2015, Ms. Sundstrom was promoted to Chief Financial Officer. Ms. Sundstrom has extensive financial accounting experience with Automatic Data Processing (ADP) and Mitsubishi Consumer Electronics. She began her career with a small public accounting firm, Carnevale & Co., P.C., was Senior Accountant at Mitsubishi Consumer Electronics responsible for the close process and was Accounting Manager for the Benefit Services division of ADP and assisted in the documentation of internal controls for Sarbanes-Oxley compliance. Ms. Sundstrom holds a Bachelor of Science in Accounting from the State University of New York at Geneseo.

Shri P. Parikh joined the Company as President, Healthcare in May of 2018. Mr. Parikh most recently served as Vice President, Sales and Marketing at Molnycke Health Care. Prior to Molnlycke, Shri was the Director of National Accounts at Stryker, a leading medical technology company with products and services in Orthopaedics, Medical and Surgical Equipment, and Neurotechnology and Spine. Mr. Parikh began his career in sales at Bristol-Myers Squibb and held various roles with increasing sales, marketing and corporate accounts responsibility at Guidant and St. Jude Medical before joining Stryker. Mr. Parikh holds a Bachelor of Arts degree in Medical Ethics and Economics from Davison College, a Master of Business Administration from Jacksonville University and an Advanced Management Program degree from the University of Chicago.

Peter Stegagno joined the Company as Vice President, Operations in March 2006. In September 2018, Mr. Stegagno was promoted to Chief Operating Officer. Mr. Stegagno brings to the Company sixteen years' experience in the medical device market encompassing manufacturing, design and development, quality assurance and international and domestic regulatory affairs. He most recently served as Vice President of Quality and Regulatory Affairs for Elekta,

and other medical device companies including Genzyme Biosurgery. Before focusing on the medical field, Mr. Stegagno enjoyed a successful career encompassing production roles in the space industry, including avionics guidance systems for military applications and control computers for the space shuttle. Mr. Stegagno graduated from Tufts University with a Bachelor of Science degree in Chemical Engineering.

Iulian Cioanta, PhD joined the Company in June 2007 as Vice President of Research and Development. In September 2018, Dr. Cioanta was promoted to Chief Science and Technology Officer. Dr. Cioanta most recently served as Business Unit Manager with Cordis Endovascular, a Johnson & Johnson company. Prior to that, Dr. Cioanta worked as Director of Development Engineering with Kensey Nash Corporation, Research Manager at AgroMed Inc. and Project Manager and Scientist with the Institute for the Design of Research Apparatus. Dr. Cioanta also worked in academia at Polytechnic University of Bucharest in Romania, Leicester University in the United Kingdom and Duke University in the United States. Dr. Cioanta received a Master of Science degree in Mechanical Engineering and Technology form the Polytechnic University of Bucharest and he earned his PhD degree in Biomedical Engineering from Duke University in the field of extracorporeal shock wave lithotripsy.

John F. Nemelka joined the Company as a member of the board of directors in October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Nemelka founded NightWatch Capital Group, LLC, an investment management business, and served as its Managing Principal since its incorporation in July 2001 until its liquidation in December 2015. From 1997 to 2000, he was a Principal at Graham Partners, a private investment firm and affiliate of the privately-held Graham Group. From 2000 to 2001, Mr. Nemelka was a Consultant to the Graham Group. Mr. Nemelka brings to our board of directors a diverse background with both financial and operations experience. He holds a B.S. degree in Business Administration from Brigham Young University and an M.B.A. degree from the Wharton School at the University of Pennsylvania.

Alan L. Rubino joined the Company as a member of the board of directors in September of 2013. Mr. Rubino has served as President and Chief Executive Officer of Emisphere Technologies, Inc. since September, 2012. Previously, Mr. Rubino served as the CEO and President of New American Therapeutics, Inc., CEO and President of Akrimax Pharmaceuticals, LLC., and President and COO of Pharmos Corporation. Mr. Rubino has continued to expand upon a highly successful and distinguished career that included Hoffmann-La Roche Inc. where he was a member of the U.S. Executive and Operating Committees and a Securities and Exchange Commission (SEC) corporate officer. During his Roche tenure, he held key executive positions in marketing, sales, business operations, supply chain and human resource management, and was assigned executive committee roles in marketing, project management, and globalization. Mr. Rubino also held senior executive positions at PDI, Inc. and Cardinal Health. He holds a BA in economics from Rutgers University with a minor in biology/chemistry and completed post-graduate educational programs at the University of Lausanne and Harvard Business School. Mr. Rubino serves on the boards of Aastrom Biosciences, Inc. and Genisphere, LLC and is also on the Rutgers University Business School Board of Advisors.

A. Michael Stolarski joined the Company as a member of the board of directors in April 2016. Mr. Stolarski founded Premier Shockwave, Inc. in October 2008 and has since served as its President & CEO. From 2005 to 2008, Mr. Stolarski was the Vice President of Business Development and, previously, Acting CFO of SANUWAVE, Inc. From 2001 to 2005, he was the President Orthopaedic Division and Vice President of Finance for HealthTronics Surgical Services, Inc. From 1994 to 2001, he was the CFO and Controller of the Lithotripsy Division, Internal Auditor, and Paralegal of Integrated Health Services, Inc. Mr. Stolarski brings to our board an in-depth understanding of the orthopaedic and podiatric shockwave market. In addition to being a Certified Public Accountant in the state of Maryland (inactive), he holds a M.S. in Finance from Loyola College, Baltimore a B.S. in Accounting and a B.S. in Finance from the University of Maryland, College Park.

Dr. Maj-Britt Kaltoft joined the Company as a member of the board of directors in June 2017. Since January 2017, Dr. Kaltoft heads the business development and patent functions at the Danish State Serum Institute, an institution under the Danish Ministry of Health. From 2011 to 2016, she was the Vice President Corporate Alliance Management, Licensing Director and Business Development with Novo Nordisk headquartered in Bagsvaerd, Denmark. She has obtained outstanding results in the areas of business development, licensing and alliance management in the pharmaceutical and biotech industry at Lundbeck, Nycomed, and EffRx. Dr. Kaltoft brings 20 years of international specialization in development and successful execution of business development strategies, contractual structures and alliance management within all sectors of the life science industry.

Summary Compensation Table for Fiscal Years 2017 and 2016

The following table provides certain information concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2017 and 2016.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(3)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II Chairman of the Board and Chief Executive Officer (principal executive officer)	2017	$120,000(1)	-	$130,882(2)	-	-	-	-	$250,882
	2016	$120,000(1)	-	$114,021(2)	-	-	-	-	$234,021
Lisa E. Sundstrom Chief Financial Officer (principal financial officer)	2017	$115,000	-	$88,352(2)	-	-	-	$12,652	$216,004
	2016	$115,000	-	$81,444(2)	-	-	-	$13,284	$209,728
Peter Stegano Vice President, Operations	2017	$200,000	-	$88,352(2)	-	-	-	$13,498	$301,850
	2016	$200,000	-	$81,444(2)	-	-	-	$13,339	$294,783
Iulian Cioanta Vice President, Research and Development	2017	$200,000	-	$88,352(2)	-	-	-	$19,583	$307,935
	2016	$200,000	-	$81,444(2)	-	-	-	$19,892	$301,336

(1) Mr. Richardson has been the Company's Chairman of the Board since the Company's inception. Since 2014, Mr. Richardson was also our Acting Chief Executive Officer, and on November 30, 2018, Mr. Richardson became our Chief Executive Officer. We continue to compensate Mr. Richardson as a director as described in "Discussion of Director Compensation" below, however we pay him an additional $10,000 per month in recognition of his additional role as Acting Chief Executive Officer.
(2) This dollar amount reflects the full fair value of the grant at the date of issuance and is recognized for financial statement reporting purposes with respect to each fiscal year over the vesting terms in accordance with ASC 718-10.
(3) Includes health, dental, life and disability insurance premiums and 401(k) matching contributions.

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. (the "2006 Plan"). On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (previously defined as the "Stock Incentive Plan"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include nonstatutory options as well as qualified incentive stock options. The Stock Incentive Plan is currently administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are nonstatutory options which vest over a period of up to three years, and have a maximum ten year term. The options are granted at an exercise price equal to the fair market value of the common stock on the date of the grant which is approved by the board of directors of the Company. The Stock Incentive Plan had 22,500,000 shares of common stock reserved for grant at December 31,2017 and 2016.

The terms of the options granted under the Stock Incentive Plan expire as determined by individual option agreements (or on the tenth anniversary of the grant date), unless terminated earlier on the first to occur of the following: (1) the date on which the participants service with the Company is terminated by the Company for cause; (2) 60 days after the participants death; or (3) 60 days after the termination of the participants service with the Company for any reason other than cause or the participants death; provided that, if during any part of such 60 day period the option is not exercisable solely because of specified securities law restrictions, the option will not expire until the earlier of the expiration date or until it has been exercisable for an aggregate period of 60 days after the termination of the participants service with the Company. The options vest as provided for in each individuals option agreement and the exercise prices for the options are determined by the board of directors at the time the option is granted; provided that the exercise price shall in no event be less than the fair market value per share of the Company's Common Stock on the grant date. In the event of any change in the Common Stock underlying the options, by reason of any merger or exchange of shares of common stock, the board of directors shall make such substitution or adjustment as it deems to be equitable to (1) the class and number of shares underlying such option, (2) the exercise price applicable to such option, or (3) any other affected terms of such option.

In the event of a change of control, unless specifically modified by an individual option agreement: (1) all options outstanding as of the date of such change of control will become fully vested; and (2) notwithstanding (1) above, in the event of a merger or share exchange, the board of directors may, in its sole discretion, determine that any or all options granted pursuant to the Stock Incentive Plan will not vest on an accelerated basis if the board of directors, the surviving corporation or the acquiring corporation, as the case may be, has taken such action as in the opinion of the board of directors is equitable or appropriate to protect the rights and interests of the participants under the Stock Incentive Plan.

On December 31, 2017, there were 2,238,281 shares of common stock available for grant under the Stock Incentive Plan. For the years ended December 31, 2017 and 2016, there were 2,700,000 and 4,067,800 options, respectively, granted to the Company's executive officers under the Stock Incentive Plan.

Outstanding Equity Awards at 2017 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2017.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Kevin A. Richardson, II Chairman of the Board and Chief Executive Officer (principal executive officer)	115,000(1)	-	-	$0.35	02/21/2023	-	-	-	-
	452,381(3)	-	-	$0.11	10/1/2025	-	-	-	-
	297,619(3)	-	-	$0.06	10/1/2025	-	-	-	-
	700,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	594,300(5)	-	-	$0.18	11/9/2026	-	-	-	-
	900,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	640,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
Lisa Sundstrom Chief Financial Officer (principal	65,000(1)	-	-	$0.35	02/21/2023	-	-	-	-
	25,000(2)	-	-	$0.55	5/7/2024	-	-	-	-

executive officer)									
	301,587(3)	-	-	$0.11	10/1/2025	-	-	-	-
	198,413(3)	-	-	$0.06	10/1/2025	-	-	-	-
	500,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	424,500(5)	-	-	$0.18	11/9/2026	-	-	-	-
	600,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	440,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
Peter Stegano	333,644(1)	-	-	$0.35	02/21/2023	-	-	-	-
Vice President, Operations	50,000(2)	-	-	$0.55	5/7/2024	-	-	-	-
	301,587(3)	-	-	$0.11	10/1/2025	-	-	-	-
	198,413(3)	-	-	$0.06	10/1/2025	-	-	-	-
	500,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	424,500(5)	-	-	$0.18	11/9/2026	-	-	-	-
	600,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	440,000(7)	-	-	$0.11	3/17/2019	-	-	-	-
Iulian Cioanta	296,241(1)	-	-	$0.35	02/21/2023	-	-	-	-
Vice President, Research and Development	50,000(2)	-	-	$0.55	5/7/2024	-	-	-	-
	301,587(3)	-	-	$0.11	10/1/2025	-	-	-	-
	198,413(3)	-	-	$0.06	10/1/2025	-	-	-	-
	500,000(4)	-	-	$0.04	6/16/2026	-	-	-	-
	424,500(5)	-	-	$0.18	11/9/2026	-	-	-	-
	600,000(6)	-	-	$0.11	6/14/2027	-	-	-	-
	440,000(7)	-	-	$0.11	3/17/2019	-	-	-	-

(1) On February 21, 2013, the Company, by mutual agreement with all active employees and directors of the Company, cancelled options granted to the active employees and directors in the year ended December 31, 2011 and prior. In exchange for these options, the active employees and directors received new options to purchase shares of common stock at an exercise price of $0.35 per share. The Company cancelled all options which were previously granted to Mr. Richardson, Ms. Sundstrom, Mr. Stegagno and Mr. Cioanta. The Company granted Mr. Richardson 115,000 options, Ms. Sundstrom 65,000 options, Mr. Stegagno 333,644 options and Mr. Cioanta 296,241 options on February 21, 2013 which vests one-third at grant date, one-third on February 21, 2014 and one-third on February 21, 2015.

(2) The Company granted Ms. Sundstrom 25,000 options, Mr. Stegagno 50,000 options and Mr. Cioanta 50,000 options on May 7, 2014 which vests one-third at grant date, one-third on May 7, 2015 and one-third on May 7, 2016.

(3) The Company granted Mr. Richardson 750,000 options, Ms. Sundstrom 500,000 options, Mr. Stegagno 500,000 options and Mr. Cioanta 500,000 options on October 1, 2015 which vests at grant date.

(4) The Company granted Mr. Richardson 700,000 options, Ms. Sundstrom 500,000 options, Mr. Stegagno 500,000 options and Mr. Cioanta 500,000 options on June 16, 2016 which vests at grant date.

(5) The Company granted Mr. Richardson 594,300 options, Ms. Sundstrom 424,500 options, Mr. Stegagno 424,500 options and Mr. Cioanta 424,500 options on November 9, 2016 which vests at grant date.

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(6) The Company granted Mr. Richardson 900,000 options, Ms. Sundstrom 600,000 options, Mr. Stegagno 600,000 options and Mr. Cioanta 600,000 options on June 15, 2017 which vests at grant date.

(7) The Company granted Mr. Richardson 640,000 warrants, Ms. Sundstrom 440,000 warrants, Mr. Stegagno 440,000 warrants and Mr. Cioanta 440,000 warrants on December 11, 2017 which vests at grant date.

Director Compensation Table for Fiscal 2017

The following table provides certain information concerning compensation for each director during the fiscal year ended December 31, 2017.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Kevin A. Richardson, II (1)	$24,000	-	$130,882	-	-	-	$154,882
John F. Nemelka	$24,000	-	$42,530	-	-	-	$66,530
Alan L. Rubino	$24,000	-	$42,530	-	-	-	$66,530
A. Michael Stolarski	$24,000	-	$42,530	-	-	-	$66,530
Maj-Britt Kaltoft	$13,000	-	$42,530	-	-	-	$55,530

(1) Mr. Richardson has been the Company's Chairman of the Board since the Company's inception. Since 2014, Mr. Richardson was also our Acting Chief Executive Officer, and on November 30, 2018, Mr. Richardson became our Chief Executive Officer. We continue to compensate Mr. Richardson as a director as described in "Discussion of Director Compensation" below, however through November 29, 2018 we paid him an additional $10,000 per month in recognition of his additional role as Acting Chief Executive Officer. Starting on November 30, 2018, Mr. Richardson is entitled to an annual base salary of $350,000 with the right to change the salary based on performance reviews and recommendations from the compensation committee of the Board of Directors of the Company. Mr. Richardson is also eligible to earn an annual bonus award of up to one hundred percent of his annual salary based on the

achievement of certain performance goals established by the Company's board of directors. Mr. Richardson is also eligible to receive a one-time sign on bonus of $145,833.33 is certain company goals are met as established by the Board of Directors of the Company.

The following are the aggregate number of option awards outstanding that have been granted to each of our non-employee directors as of December 31, 2017: Kevin A. Richardson, II 3,059,300; John F. Nemelka 1,034,800; Alan L. Rubino 1,019,800; A. Michael Stolarski 669,800 and Maj-Britt Kaltoft 300,000.

Discussion of Director Compensation

Effective January 1, 2017, the Company began to compensate its three outside directors at an annual rate of $24,000 each. On June 15, 2017, the Company issued 900,000 options to purchase the Company's common stock at $0.11 per share to non-employee director Kevin A. Richardson II and the Company issued 300,000 to purchase the Company's common stock at $0.11 per share to non-employee directors John F. Nemelka, Alan L. Rubino, A. Michael Stolarski and Maj-Britt Kaltoft. On November 9, 2016, the Company issued 594,300 options to purchase the Company's common stock at $0.18 per share to non-employee director Kevin A. Richardson II and the Company issued 169,800 to purchase the Company's common stock at $0.18 per share to non-employee directors John F. Nemelka, Alan L. Rubino and A. Michael Stolarski. On June 16, 2016, the Company issued 700,000 options to purchase the Company's common stock at $0.04 per share to non-employee director Kevin A. Richardson II and the Company issued 200,000 to purchase the Company's common stock at $0.04 per share to non-employee directors John F. Nemelka, Alan L. Rubino and A. Michael Stolarski. On October 1, 2015, the Company issued 452,381 options to purchase the Company's common stock at $0.11 per share and 297,619 options to purchase the Company's common stock at $0.50 per share to non-employee director Kevin A. Richardson II and the Company issued 150,795 options to purchase the Company's common stock at $0.11 per share and 99,205 options to purchase the Company's common stock at $0.50 per share to non-employee directors John F. Nemelka and Alan L. Rubino. On September 3, 2013, the Company issued 100,000 options to purchase the Company's common stock at $0.65 per share to non-employee director Alan L. Rubino. On February 21, 2013, the Company, by mutual agreement with all the active employees and directors of the Company, cancelled options granted to the active employees and directors in the year ended December 31, 2011 and prior. In exchange for these options, the active employees and directors received new options to purchase shares of common stock at an exercise price of $0.35 per share. Kevin A. Richardson, II, and John F. Nemelka, each cancelled 15,000 options and were each issued 115,000 options at an exercise price of $0.35 per share.

Committee Interlocks and Insider Participation

The Compensation Committee is comprised of Alan L. Rubino, Kevin A. Richardson, II, A. Michael Stolarski and Maj-Britt Kaltoft. Mr. Richardson and Mr. Stolarski have had certain relationships and related party transactions described further in the section entitled "Certain Relationships and Related Transactions Related Party Transactions." During 2017, none of our executive officers served as a director or member of a compensation committee (or other committee serving an equivalent function) of any other entity whose executive officers served as a director or member of the Compensation Committee.

CORPORATE GOVERNANCE AND BOARD MATTERS

The Company adopted a formal Corporate Governance policy in January 2012 which included establishing formal board committees and a code of conduct for the board of directors and the Company.

The Board of Directors

Recent Developments

The Company's current board of directors consists of five members, two of whom have been determined by the board to be "independent" as defined under the rules of the Nasdaq stock market. The Company expects to add additional independent directors in 2018.

Boards Leadership Structure

The Company's board of directors elects the Company's chief executive officer and its chairman, and each of these positions may be held by the same person or may be held by two persons. The chairman's primary responsibilities are to manage the board and serve as the primary liaison between the board of directors and the chief executive officer, while the primary responsibility of the chief executive officer is to manage the day-to-day affairs of the Company, taking into account the policies and directions of the board of directors. Such an arrangement promotes more open and robust communication among the board, and provides an efficient decision making process with proper independent oversight. The Company's board of directors has determined that it is currently in the best interest of the Company and its shareholders to combine the roles of chairman of the board and chief executive officer.

The Company believes, however, that there is no single leadership structure that is the best and most effective in all circumstances and at all times. Accordingly, the board of directors retains the authority to later combine these roles if doing so would be in the best interests of the Company and its shareholders.

The Company's board of directors is authorized to have an audit committee, a compensation committee and a nominating and corporate governance committee, to assist the Company's board of directors in discharging its responsibilities. The Company's current board of directors consists of five members, two of whom has been determined by the board to be "independent" as defined under the rules of the Nasdaq stock market. The board of directors has determined that Mr. Richardson, Mr. Nemelka and Mr. Stolarski are not independent under the applicable marketplace rules of the Nasdaq stock market and Rule 10A-3 under the Exchange Act. The Company expects to add additional independent directors in 2018

Boards Role in Risk Oversight

While the Company's management is responsible for the day-to-day management of risk to the Company, the board of directors has broad oversight responsibility for the Company's risk management programs. The various committees of

the board of directors assist the board of directors in fulfilling its oversight responsibilities in certain areas of risk. In particular, the audit committee focuses on financial and enterprise risk exposures, including internal controls, and discusses with management and the Company's independent registered public accountants the Company's policies with respect to risk assessment and risk management. The compensation committee is responsible for considering those risks that may be implicated by the Company's compensation programs and reviews those risks with the Company's board of directors and chief executive officer.

Audit Committee

The current members of the Company's audit committee are John F. Nemelka (Chairperson), Kevin A. Richardson, II, and A. Michael Stolarski. Mr. Nemelka, who chairs the committee, has been determined by the board of directors to be an audit committee financial expert as defined pursuant to the rules of the SEC. Pursuant to the Company's Audit Committee Charter, the audit committee is required to consist of at least two independent directors. The Company expects to add additional independent directors to the board of directors in 2018.

The audit committee operates under a written charter adopted by the board of directors which is available on the Company's website at www.sanuwave.com. The primary responsibility of the audit committee is to oversee the Company's financial reporting process on behalf of the board of directors. Among other things, the audit committee is responsible for overseeing the Company's accounting and financial reporting processes and audits of the Company's financial statements, reviewing and discussing with the independent auditors the critical accounting policies and practices for the Company, engaging in discussions with management and the independent auditors to assess risk for the Company and management thereof, and reviewing with management the effectiveness of the Company's internal controls and disclosure controls and procedures. The audit committee is directly responsible for the appointment, compensation, retention and oversight of the work of the Company's independent auditors, currently Marcum LLP, including the resolution of disagreements, if any, between management and the auditors regarding financial reporting. In addition, the audit committee is responsible for reviewing and approving any related party transaction that is required to be disclosed pursuant to Item 404 of Regulation S-K promulgated under the Exchange Act.

Compensation Committee

The current members of the Company's compensation committee are Alan L. Rubino (Chairperson), Kevin A. Richardson II, A. Michael Stolarski and Maj-Britt Kaltoft. The primary purpose of the compensation committee is to discharge the responsibilities of the board of directors relating to compensation of the Company's executive officers. Pursuant to the Company's Compensation Committee Charter, the compensation committee is required to consist of at least two independent directors. The Company expects to add additional independent directors to the board of directors in 2018.

The compensation committee operates under a written charter adopted by the board of directors which is available on the Company's website at www.sanuwave.com. Specific responsibilities of the compensation committee include reviewing and recommending approval of compensation of the Company's named executive officers, administering the Company's stock incentive plan, and reviewing and making recommendations to the Company's board of directors with respect to incentive compensation and equity plans.

Nominating and Corporate Governance Committee

The current members of the Company's nominating and corporate governance committee are Maj-Britt Kaltoft (Chairperson), Kevin A. Richardson, II, John F. Nemelka, and Alan L. Rubino. Pursuant to the Company's Nominating and Corporate Governance Committee Charter, the nominating and corporate governance committee is required to consist of at least two independent directors. The Company expects to add additional independent directors to the board of directors in 2018.

The nominating and corporate governance committee operates under a written charter adopted by the board of directors which is available on the Company's website at www.sanuwave.com. Specific responsibilities of the nominating and corporate governance committee include: identifying and recommending nominees for election to the Company's board of directors; developing and recommending to the board of directors the Company's corporate governance principles; overseeing the evaluation of the board of directors; and reviewing and approving compensation

for non-employee members of the board of directors.

The nominating and corporate governance committees charter outlines how the nominating and corporate governance committee fulfills its responsibilities for assessing the qualifications and effectiveness of the current board members, assessing the needs for future board members, identifying individuals qualified to become members of the board and its committees, and recommending candidates for the board of directors selection as director nominees for election at the next annual or other properly convened meeting of shareholders.

The nominating and corporate governance committee considers director candidates recommended by shareholders for nomination for election to the board of directors. The committee applies the same standards in considering director candidates recommended by the shareholders as it applies to other candidates. Any shareholder entitled to vote for the election of directors may recommend a person or persons for consideration by the committee for nomination for election to the board of directors. The Company must receive written notice of such shareholders recommended nominees(s) no later than January 31st of the year in which the shareholder wishes such recommendation to be considered by the committee in connection with the next meeting of shareholders at which the election of directors will be held. To submit a recommendation, a shareholder must give timely notice thereof in writing to the Secretary of the Company. A shareholders notice to the Secretary shall set forth: (i) the name and record address of the shareholder making such recommendation and any other shareholders known by such shareholder to be supporting such recommendation; (ii) the class and number of shares of the Company which are beneficially owned by the shareholder and by any other shareholders known by such shareholder to be supporting such recommendation; (iii) the name, age and five year employment history of such recommended nominee; (iv) the reasons why the shareholder believes the recommended nominee meets the qualifications to serve as a director of the Company; and (v) any material or financial interest of the shareholder and, if known, the recommended nominee in the Company.

Shareholder Communications with the Board of Directors

The board of directors has implemented a process for shareholders to send communications to the board of directors. Shareholders who wish to communicate directly with the board of directors or any particular director should deliver any such communications in writing to the Secretary of the Company. The Secretary will compile any communications they receive from shareholders and deliver them periodically to the board of directors or the specific directors requested. The Secretary of the Company will not screen or edit such communications, but will deliver them in the form received from the shareholder.

Code of Conduct and Ethics

It is the Company’s policy to conduct its affairs in accordance with all applicable laws, rules and regulations of the jurisdictions in which it does business. The Company has adopted a code of business conduct and ethics with policies and procedures that apply to all associates (all employees are encompassed by this term, including associates who are officers) and directors, including the chief executive officer, chief financial officer, controller, and persons performing similar functions.

The Company has made the code of business conduct and ethics available on its website at www.sanuwave.com. If any substantive amendments to the code of business conduct and ethics are made or any waivers are granted, including any implicit waiver, the Company will disclose the nature of such amendment or waiver on its website or in a report on Form 8-K.

No Family Relationships Among Directors and Officers

There are no family relationships between any director or executive officer of the Company and any other director or executive officer of the Company.

Director Independence

Our board of directors has determined that Alan L. Rubino and Dr. Maj-Britt Kaltoft qualify as independent directors based on the Nasdaq Stock Market definition of “independent director.”

Limitation of Directors Liability and Indemnification

The Nevada Revised Statutes authorize corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Nevada law.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act of 1933, as amended. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is one of our officers or directors, is involved in a legal proceeding of any nature.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of our equity securities which are registered pursuant to Section 12 of the Exchange Act, to file with the SEC initial reports of ownership and reports of changes in ownership of our equity securities. Officers, directors and greater than 10% shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of the Forms 3, 4 and 5 (and amendments thereto) furnished to us for our fiscal year ended December 31, 2017, we have determined that our directors, officers and greater than 10% beneficial owners complied with all applicable Section 16 filing requirements.

Disclosure of Commission Position on Indemnification of Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information, as of December 3, 2018, with respect to the beneficial ownership of the Company's outstanding Common Stock by (i) any holder of more than five percent (5.0%), (ii) each of the Company's executive officers and directors, and (iii) the Company's directors and executive officers as a group.

Name of Beneficial Owner (1)	Number of Shares Beneficially Owned	Percent of Shares Outstanding (2)
Kevin A. Richardson II (4)	17,564,160	10.6%
A. Michael Stolarski (3)	16,789,333	10.0%
Peter Stegagno (5)	4,261,780	2.7%
Iulian Cioanta (6)	3,576,146	2.3%
Lisa E. Sundstrom (7)	3,304,500	2.1%
John F. Nemelka (8)	1,596,055	1.0%
Alan Rubino (9)	1,569,800	1.0%
Maj-Britt Kaltoft (10)	850,000	0.5%
All directors and executive officers as a group (8 persons)	49,511,774	30.2%
5% Beneficial Owner:		
Jerome Gildner (11)	13,333,334	8.2%
John McDermott (11)	12,575,756	7.8%
Nicholas Carosi III (11)	11,818,182	7.2%
James McGraw (11)	11,610,694	7.1%

(1)
Unless otherwise noted, each beneficial owner has the same address as us.
(2)
Applicable percentage ownership is based on 155,533,303 shares of common stock outstanding as of December 3, 2018, "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of December 3, 2018. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.
(3)
Includes options to purchase up to 1,019,800 shares of common stock, warrants to purchase up to 7,499,452 shares of common stock and 4,545,455 common shares available upon conversion of convertible promissory note.
(4)
Includes options to purchase up to 4,159,300 shares of common stock, warrants to purchase up to 3,222,583 shares of common stock and 2,363,636 common shares available upon conversion of convertible promissory note. In addition, this amount includes 138,782 shares of common stock owned directly by Prides Capital Fund I, L.P. Prides Capital Partners LLC is the general partner of Prides Capital Fund I, L.P. and Mr. Richardson is the controlling shareholder of Prides Capital Partners LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. Richardson has also been deputized by Prides Capital Partners LLC to serve

on the board of directors of the Company. Mr. Richardson disclaims beneficial ownership of all such securities except to the extent of any indirect pecuniary interest (within the meaning of Rule 16a-1 of the Exchange Act) therein.

(5)

Consists of options to purchase up to 3,158,144 shares of common stock, warrants to purchase up to 771,818 shares of common stock and 331,818 common shares available upon conversion of convertible promissory note.

(6)

Consists of options to purchase up to 3,120,741 shares of common stock and warrants to purchase up to 440,000 shares of common stock.

(7)

Consists of options to purchase up to 2,864,500 shares of common stock and warrants to purchase up to 440,000 shares of common stock.

(8)

Includes options to purchase up to 1,384,800 shares of common stock and warrants to purchase up to 200,000 shares of common stock.

(9)

Includes options to purchase up to 1,369,800 shares of common stock and warrants to purchase up to 200,000 shares of common stock.

(10)

Includes options to purchase up to 650,000 shares of common stock and warrants to purchase up to 200,000 shares of common stock.

(11)

Based on records of the Company.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Party Transactions

Other than as described below, since January 1, 2017, there have been no transactions with related persons required to be disclosed in this report.

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

On December 29, 2017, the Company entered into a line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The agreement established a line of credit in the amount of $370,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand. The outstanding balance as of December 31, 2017 with accrued interest was $370,179 and $0 interest was paid for the period ending December 31, 2017.

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder.

On December 11, 2017, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000 shares of common stock at an exercise price of $0.11 per share. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company's board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company's board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants.

On March 27, 2017, the Company began offering subscriptions for 10% convertible promissory notes (the "10% Convertible Promissory Notes") to selected accredited investors. The Company intends to use the proceeds from the 10% Convertible Promissory Notes for working capital and general corporate purposes. The initial offering closed on August 15, 2017, at which time $55,000 aggregate principal amount of 10% Convertible Promissory Notes were issued and the funds paid to the Company. Subsequent offerings were closed on November 3, 2017, November 30, 2017, and December 21, 2017, at which times $1,069,440, $259,310 and $150,000, respectively, aggregate principal amounts of 10% Convertible Promissory Notes were issued and the funds paid to the Company. The 10% Convertible Promissory Notes include a warrant agreement (the "Class N Warrant Agreement") to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount, by (ii) $0.11. The Class N Warrant Agreement

expires March 17, 2019. On November 3, 2017, the Company issued 10,222,180 Class N Warrants in connection with the initial and second closings of 10% Convertible Promissory Notes. On November 30, 2017, and December 21, 2017, the Company issued 2,357,364 and 1,363,636, respectively, Class N Warrants in connection with the closings of 10% Convertible Promissory Notes. A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $330,000. A. Michael Stolarski and Kevin A. Richardson II, both members of the Company's board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The 10% Convertible Promissory Notes associated with these subscriptions were issued in January 2018.

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 355,000,000 shares, of which 350,000,000 shares are designated as Common Stock and 5,000,000 shares are designated as preferred stock. As of December 3, 2018, there were issued and outstanding:

155,533,303 shares of Common Stock,

warrants to purchase 103,504,427 shares of Common Stock at a weighted average exercise price of $0.09 per share, and

stock options to purchase 31,673,385 shares of Common Stock at a weighted average exercise price of $0.29 per share.

The following summary of the material provisions of our Common Stock, preferred stock and warrants is qualified by reference to the provisions of our articles of incorporation and bylaws and the forms of warrant included or incorporated by reference as exhibits to the registration statement of which this prospectus is a part.

Common Stock

All shares of our Common Stock have equal voting rights and, when validly issued and outstanding, have one vote per share in all matters to be voted upon by the stockholders. Cumulative voting in the election of directors is not allowed, which means that the holders of more than 50% of the outstanding shares can elect all the directors if they choose to do so and, in such event, the holders of the remaining shares will not be able to elect any directors. The affirmative vote of a plurality of the shares of Common Stock voted at a stockholders meeting where a quorum is present is required to elect directors and to take other corporate actions. Holders of our Common Stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds. However, the current policy of our board of directors is to retain earnings, if any, for the operation and expansion of the Company. Upon liquidation, dissolution or winding-up, the holders of our Common Stock are entitled to share ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities and the liquidation preference of any outstanding preferred stock. The holders of our Common Stock have no preemptive, subscription, redemption or conversion rights. All issued and outstanding shares of Common Stock are, and the Common Stock reserved for issuance upon exercise of our stock options and warrants will be, when issued, fully-paid and non-assessable.

Preferred Stock

Our articles of incorporation authorize the issuance of up to 5,000,000 shares of “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by our board of directors.

Warrants

The following is a brief summary of material provisions of the warrants related to the shares of common stock offered for resale and issuable upon the exercise of such warrants issued to the selling stockholders described herein.

Exercise Price and Terms. Each warrant entitles the holder thereof to purchase at any time until March 17, 2019, at a price of $0.08 per share, subject to certain adjustments referred to below, shares of our Common Stock. The holder of any warrant may exercise such warrant by surrendering the warrant to us, with the notice of exercise properly

completed and executed, together with payment of the exercise price. The warrants may be exercised at any time in whole or in part at the applicable exercise price until expiration of the warrants. No fractional shares will be issued upon the exercise of the warrants.

Adjustments. The exercise price and the number of shares of Common Stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of certain events, including stock dividends, stock splits, combinations or reclassifications of the Common Stock. Additionally, an adjustment would be made in the case of a reclassification or exchange of Common Stock, consolidation or merger of our Company with or into another corporation (other than a consolidation or merger in which we are the surviving corporation) or sale of all or substantially all of our assets in order to enable holders of the warrants to acquire the kind and number of shares of stock or other securities or property receivable in such event by a holder of the number of shares of Common Stock that might otherwise have been purchased upon the exercise of the warrant. No adjustment to the number of shares and exercise price of the shares subject to the warrants will be made for dividends (other than stock dividends), if any, paid on our Common Stock.

Transfer, Exchange and Exercise. The warrants may be presented to us for exchange or exercise at any time on or prior to March 17, 2019, at which time the warrants become wholly void and of no value. Prior to any transfer of the warrants the holder must notify us of the same and, if subsequently requested, provide a legal opinion regarding the transfer to us.

Warrantholder Not a Stockholder. The warrants do not confer upon holders any voting, dividend or other rights as a shareholder of our Company.

Trading Information

Our shares of Common Stock are currently quoted in the over-the-counter market on the OTCQB under the symbol “SNWV”.

Transfer Agent

The transfer agent and registrar for our Common Stock and preferred stock is Action Stock Transfer Corp., 7069 S. Highland Drive, Suite 300, Salt Lake City, Utah 84121.

SHARES AVAILABLE FOR FUTURE SALE

As of December 3, 2018, we had 155,533,303 shares of Common Stock outstanding, not including shares issuable upon the exercise of outstanding warrants, stock options and other convertible securities. All shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless they are purchased by our “affiliates,” as that term is defined in Rule 144 promulgated under the Securities Act.

The outstanding shares of our Common Stock not included in this prospectus will be available for sale in the public market as follows:

Public Float

Of our outstanding shares, 49,511,774 shares are beneficially owned by executive officers, directors and affiliates of the Company. The remaining 106,021,529 shares constitute our public float which, based on the last sale price of our Common Stock reported on the OTC Bulletin Board on December 3, 2018, equaled approximately $25,445,167.

Rule 144

In general, under Rule 144, as currently in effect, a person who has beneficially owned shares of our Common Stock for at least six (6) months, including the holding period of prior owners other than affiliates, is entitled to sell his or her shares without any volume limitations; an affiliate, however, can sell such number of shares within any three-month period as does not exceed the greater of:

- 1% of the number of shares of our Common Stock then outstanding, which equaled 1,555,333 shares as of December 3, 2018, or

- the average weekly trading volume of our Common Stock, assuming our shares are then traded on a national securities exchange, during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 are also subject to manner-of-sale provisions, notice requirements and the availability of current public information about us.

LEGAL MATTERS

Certain legal matters will be passed upon for us by Hutchison & Steffen, LLC, Las Vegas, Nevada.

EXPERTS

The consolidated financial statements as of December 31, 2017 and 2016 and for the years then ended included in this prospectus and in the registration statement have been so included in reliance on the report of Cherry Bekaert LLP, an independent registered public accounting firm, (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

INTEREST OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the Common Stock was employed on a contingency basis, or had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC to register resale of shares of our Common Stock being offered by this prospectus. For further information with respect to us and our Common Stock, please see the registration statement on Form S-1 and the exhibits thereto. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website, http://www.sec.gov that contains reports, proxy statements and information statements and other information regarding registrants that file electronically with the SEC, including us. Our SEC filings are also available to the public from commercial document retrieval services. Information contained on our website should not be considered part of this prospectus.

You may also request a copy of our filings at no cost by writing or telephoning us at:

SANUWAVE Health, Inc.
3360 Martin Farm Road, Suite 100
Suwanee, Georgia 30024
Attn: Lisa Sundstrom, Chief Financial Officer
Telephone: (770) 419-7525

PART I — FINANCIAL INFORMATION

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

	September 30, 2018	December 31, 2017
ASSETS	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$72,311	$730,184
Accounts receivable, net of allowance for doubtful accounts of $42,950 in 2018 and $92,797 in 2017	152,706	152,520
Inventory	240,973	231,532
Prepaid expenses	168,480	90,288
TOTAL CURRENT ASSETS	634,470	1,204,524
PROPERTY AND EQUIPMENT, net	72,637	60,369
OTHER ASSETS	16,497	13,917
TOTAL ASSETS	$723,604	$1,278,810
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$1,560,965	$1,496,523
Accrued expenses (Note 4)	746,083	673,600
Accrued employee compensation	364,503	1,680
Contract liabilities (Note 5)	353,115	-
Advances payable (Note 6)	144,000	310,000
Line of credit, related parties (Note 7)	524,869	370,179
Convertible promissory notes, net (Note 8)	2,548,325	455,606
Short term notes payable (Note 10)	186,981	-
Accrued interest, related parties (Note 11)	1,005,144	685,907
Warrant liability (Note 13)	1,396,199	1,943,883
Notes payable, related parties, net (Note 11)	5,335,243	5,222,259
TOTAL CURRENT LIABILITIES	14,165,427	11,159,637

NON-CURRENT LIABILITIES		
Contract liabilities (Note 5)	25,959	-
TOTAL NON-CURRENT LIABILITIES	25,959	-
TOTAL LIABILITIES	14,191,386	11,159,637
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 designated; 6,175 shares issued and 0 shares outstanding in 2018 and 2017	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 designated; 293 shares issued and 0 shares outstanding in 2018 and 2017	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 155,107,127 and 139,300,122 issued and outstanding in 2018 and 2017, respectively (Note 12)	155,107	139,300
ADDITIONAL PAID-IN CAPITAL	100,979,533	94,995,040
ACCUMULATED DEFICIT	(114,541,440)	(104,971,384)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(60,982)	(43,783)
TOTAL STOCKHOLDERS' DEFICIT	(13,467,782)	(9,880,827)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$723,604	$1,278,810

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
REVENUES				
Product	$240,759	$143,234	$703,054	$356,911
License fees	335,697	6,250	623,570	36,050
Other revenue	19,333	12,101	66,647	29,238
TOTAL REVENUES	595,789	161,585	1,393,271	422,199
COST OF REVENUES				
Product	151,624	56,415	413,447	105,027
Other	31,970	5,269	102,256	36,496
TOTAL COST OF REVENUES	183,594	61,684	515,703	141,523
GROSS MARGIN	412,195	99,901	877,568	280,676
OPERATING EXPENSES				
Research and development	661,736	266,837	1,379,517	965,084
General and administrative	2,415,106	475,377	5,391,511	1,875,891
Depreciation	5,709	5,465	16,733	17,543
Loss on sale of property and equipment	-	-	3,170	-

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

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

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

Accrued employee compensation	362,823	294
Contract liabilties	379,074	-
Interest payable, related parties	319,237	425,699
NET CASH USED BY OPERATING ACTIVITIES	(2,271,566)	(944,831)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(32,171)	-
NET CASH USED BY INVESTING ACTIVITIES	(32,171)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from convertible promissory notes, net of costs	1,159,785	-
Proceeds from line of credit, related party	280,500	-
Advances from related parties	156,000	751,616
Proceeds from note payable, product	96,708	-
Proceeds from short term note	184,750	-
Proceeds from warrant exercise	38,528	93,067
Payment on line of credit, related party	(144,500)	-
Payments on note payable, product	(96,708)	-
Payments on advances from related parties	(12,000)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,663,063	844,683
EFFECT OF EXCHANGE RATES ON CASH	(17,199)	6,803
NET DECREASE IN CASH AND CASH EQUIVALENTS	(657,873)	(93,345)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	730,184	133,571
CASH AND CASH EQUIVALENTS, END OF PERIOD	$72,311	$40,226
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$151,227	$-
NONCASH INVESTING AND FINANCING ACTIVITIES		
Cashless exercise of warrants	$118,838	$66,966
Advances from related and unrelated parties converted to Convertible promissory notes	$310,000	$-
Accounts payable converted to Convertible promissory notes	$120,000	$-
Beneficial conversion feature on convertible debt	$745,223	$-
Warrants issued for debt	$844,562	$-
Conversion of 10% convertible promissory notes	$831,000	$-

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

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

1. Nature of the Business

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

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and footnotes required by GAAP for complete financial statements. The financial information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2018.

The condensed consolidated balance sheet at December 31, 2017 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the Company's Form 10-K filed with the Securities and Exchange Commission on March 29, 2018.

2. Going Concern

The Company does not currently generate significant recurring revenue and will require additional capital during the fourth quarter of 2018 and the first quarter of 2019. As of September 30, 2018, the Company had an accumulated deficit of $114,541,440 and cash and cash equivalents of $72,311. For the nine months ended September 30, 2018 and 2017, the net cash used by operating activities was $2,271,566 and $944,831, respectively. The Company incurred a net loss of $9,470,056 for the nine months ended September 30, 2018 and a net loss of $5,537,936 for the year ended December 31, 2017. The operating losses and the events of default on the Company's convertible promissory notes (see Note 8) and the notes payable, related parties (see Note 11) indicate substantial doubt about the Company's ability

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

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

2. Going Concern (continued)

The continuation of the Company's business is dependent upon raising additional capital during the fourth quarter of 2018 and the first quarter of 2019 to fund operations. Management's plans are to obtain additional capital through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, including through tender offers for the outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. The condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

3.
Summary of Significant Accounting Policies

Recently Issued or Adopted Accounting Standards

In May 2014, the Financial Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASC 606), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASC 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASC 606 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. The standard was declared effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective method, which requires the standard to be applied to each prior period presented, or (ii) a modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to the opening retained earnings in the period of adoption. In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2018 instead of the previous effective date, which was the first quarter of fiscal 2017. This one year deferral was issued by the FASB in ASU 2015-14, Revenue from Contracts with Customers (Topic 606). The Company adopted the new standard on a modified retrospective basis as of January 1, 2018. The Company completed an assessment of customer contracts and concluded that the adoption of ASC 606 did not have a material impact on its condensed consolidated financial statements; therefore, no cumulative-effect adjustment was recorded on the adoption. The disclosures related to revenue recognition have been significantly expanded under the standard, specifically around the quantitative and qualitative information about performance obligations and disaggregation of revenue. The expanded disclosure requirements are included in this Quarterly Report on Form 10-Q (see Notes 5 and 15).

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

position or results of operations.

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

3.
Summary of Significant Accounting Policies (continued)

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

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

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

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

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

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

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

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

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

4.
Accrued expenses

Accrued expenses consist of the following:

	September 30, 2018	December 31, 2017

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

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5.
Contract liabilities

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

Contract liabilities consist of the following:

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

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

Joint Venture

On September 27, 2017, the Company entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), effective as of September 25, 2017, for a joint venture for the manufacture, sale and distribution of our dermaPACE device. Under the binding term sheet, MundiMed was to pay the Company an initial upfront distribution fee, with monthly upfront distribution fees payable thereafter over the following eighteen months. Profits from the joint venture were to be distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to

LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction. The initial upfront distribution fee was received on October 6, 2017. Monthly upfront distribution fee payments have been received through May 2018. Through September 30, 2018, the Company received aggregate payments of $372,222. In August 2018, MundiMed advised the Company that it did not anticipate being able to make further payments under the binding term sheet due to operational and cash flow difficulties. On September 14, 2018, the Company sent a letter to MundiMed informing them of a breach in our agreement regarding payment of the upfront distribution fee. On September 28, 2018, the Company received a response letter stating that the Company was in default of the agreement. On October 9, 2018, the Company sent MundiMed a letter of termination of the agreement effective as of October 8, 2018. As of September 30, 2018, the Company derecognized the contract assets and contract liabilities associated with the MundiMed contract.

6.
Advances payable

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

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

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7.
Line of credit, related parties

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

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

8.
Convertible promissory notes

In 2017, the Company began offering subscriptions for 10% convertible promissory notes (the "10% Convertible Promissory Notes") to selected accredited investors. The 10% Convertible Promissory Notes have a six month term from the subscription date and the note holders can convert the 10% Convertible Promissory Notes at any time during the term to the number of shares of Company common stock, $0.001 par value (the "Common Stock"), equal to the amount obtained by dividing (i) the amount of the unpaid principal and interest on the note by (ii) $0.11. During the nine months ended September 30, 2018, the Company issued $1,596,000 in the aggregate principal amount of 10% Convertible Promissory Notes, including $430,000 purchased by officers and directors.

The 10% Convertible Promissory Notes include a warrant agreement (the "Class N Warrant") to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount by (ii) $0.11. The Class N Warrants expire March 17, 2019. On January 10, 2018 and February 2, 2018, the Company issued 13,599,999 and 909,091, respectively, Class N Warrants in connection with the closings of 10% Convertible Promissory Notes.

Pursuant to the terms of a Registration Rights Agreement (the "Registration Rights Agreement") that the Company entered with the accredited investors in connection with the 10% Convertible Promissory Notes, the Company is required to file a registration statement that covers the shares of Common Stock issuable upon conversion of the 10% Convertible Promissory Notes or upon exercise of the Class N Warrants. The failure on the part of the Company to satisfy certain deadlines described in the Registration Rights Agreement may subject the Company to payment of certain monetary penalties. As of the date of the filing of this report the registration statement has not yet been filed. At this time the monetary penalty has been determine by management to be de minimis.

During the nine months ended September 30, 2018, the Company recorded $709,827 in debt discount for the beneficial conversion feature of the promissory notes, $808,458 in debt discount for the discount on the Class N Warrant agreement and $77,715 in debt issuance costs to be amortized over the lives of the 10% Convertible Promissory Notes. Additional debt issuance costs will be incurred and amortized over the remaining lives of the 10% Convertible Promissory Notes when Class N Warrants are issued per the engagement letter with West Park Capital. The calculated fair value of the Class N Warrants was determined using the Black-Scholes pricing model based on the following assumptions:

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

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

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8.
Convertible promissory notes (continued)

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

On January 29, 2018, the Company entered into an additional 10% Convertible Promissory Note with an accredited investor in the amount of $71,500 and issued 650,000 Class N Warrants in connection with such 10% Convertible Promissory Note. The Company intends to use the proceeds from such 10% Convertible Promissory Note for payment of services to an investor relations company and the account of the attorney updating the Registration Statement on Form S-1 of the Company filed under the Securities Act of 1933, as amended, on January 3, 2017 (File No. 333-213774), which registration statement shall also register the shares issuable upon conversion of such 10% Convertible Promissory Note and issuable upon the exercise of a Class N Warrants issued concurrently with the issuance of such 10% Convertible Promissory Note.

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

The 10% Convertible Promissory Note had an aggregate outstanding principal balance of $2,548,325 at September 30, 2018. The 10% Convertible Promissory Notes had an aggregate outstanding principal balance of $455,606, net of $1,099,861 beneficial conversion feature, warrant discount and debt issuance costs at December 31, 2017.

9.
Notes payable, product, related party

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE System in the marketplace. This agreement provides for a lease line of credit up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company’s accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company. NFS Leasing Inc. was a purchaser of the 10% Convertible Promissory Notes (see Note 8).

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

Interest expense on note payable, product totaled $0 for the three months ended September 30, 2018 and $20,909 for the nine months ended September 30, 2018, respectively.

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

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

10.
Short term notes payable

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

11.
Notes payable, related parties

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

On June 15 2015, the Company entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. During any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. Events of Default under the notes payable, related parties have occurred and are continuing on account of the failure of SANUWAVE, Inc., a Delaware corporation, a wholly owned subsidiary of the Company and the borrower under the notes payable, related parties, to make the required payments of interest which were due on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017, December 31, 2017, June 30, 2018 and September 30, 2018 (collectively, the "Defaults"). As a result of the Defaults, the notes payable, related parties have been accruing interest at the rate of 10% per annum since January 2, 2017 and continue to accrue interest at such rate. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company's patents or other intellectual property rights.

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

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

12.

Equity transactions

Conversion of 10% Convertible Promissory Notes

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

Warrant Exercise

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

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12.
Equity transactions (continued)

Cashless Warrant Exercise

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

Consulting Agreement

In April 2018, the Company verbally entered into a month-to-month consulting agreement with a consultant for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 74,714 shares of Common Stock for services performed from January through June 2018. The $20,000 was recorded as a non-cash general and administrative expense upon issuance in June 2018.

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

13.
Warrants

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

Warrant class	Outstanding as of December 31, 2017	Issued	Exercised	Expired	Outstanding as of September 30, 2018
Class F Warrants	300,000	-	-	(300,000)	-
Class G Warrants	1,503,409	-	-	(1,503,409)	-

Class H Warrants	1,988,095	-	-	(1,988,095)	-
Class I Warrants	1,043,646	-	-	(1,043,646)	-
Class K Warrants	7,200,000	-	-	-	7,200,000
Class L Warrants	63,898,173	-	(6,500,334)	-	57,397,839
Class N Warrants	13,943,180	16,402,045	(1,136,364)	-	29,208,861
Class O Warrants	6,540,000	1,509,091	(100,000)	-	7,949,091
Series A Warrants	1,561,348	-	(405,666)	-	1,155,682
	97,977,851	17,911,136	(8,142,364)	(4,835,150)	102,911,473

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13.
Warrants (continued)

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

	Exercise price/share	Expiration date
Class K Warrants	$0.08	June 2025
Class K Warrants	$0.11	August 2027
Class L Warrants	$0.08	March 2019
Class N Warrants	$0.11	March 2019
Class O Warrants	$0.11	March 2019
Series A Warrants	$0.03	March 2019

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

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

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

The estimated fair values were determined using a binomial option pricing model based on various assumptions. The Company's derivative liabilities have been classified as Level 3 instruments and are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of derivative liabilities. Various factors are considered in the pricing models the Company uses to value the warrants, including the Company's current common stock price, the remaining life of the warrants which ranged from 0.5 to 8.85 years, the volatility of the Company's common stock price which ranged from 112% to 136%, and the risk-free interest rate which ranged from 2.33% to 3.03%. In addition, as of the valuation dates, management assessed the probabilities of future financing and other re-pricing events in the binominal valuation models.

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13.
Warrants (continued)

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

	Class K Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2017	$1,616,000	$327,883	$1,943,883
Issued	-	-	-
Redeemed	-	(118,838)	(118,838)
Change in fair value	(412,800)	(16,046)	(428,846)
Warrant liability as of September 30, 2018	$1,203,200	$192,999	$1,396,199

14.
Commitments and contingencies

Operating Leases

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

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

Litigation

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

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

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15.
Revenue

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

Pursuant to ASC 606, we apply the following the five-step model:

1. Identify the contract(s) with a customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.
2. Identify the performance obligation(s) in the contract. If a contract promises to transfer more than one good or service to a customer, each good or service constitutes a separate performance obligation if the good or service is distinct or capable of being distinct.
3. Determine the transaction price. The transaction price is the amount of consideration to which the entity expects to be entitled in exchanging the promised goods or services to the customer.
4. Allocate the transaction price to the performance obligations in the contract. For a contract that has more than one performance obligation, an entity should allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which an entity expects to be entitled in exchange for satisfying each performance obligation.
5. Recognize revenue when (or as) the Company satisfies a performance obligation. For each performance obligation, an entity should determine whether the entity satisfies the performance obligation at a point in time or over time. Appropriate methods of measuring progress include output methods and input methods.

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

Product sales

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

Licensing transactions

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

Other activities

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

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15.
Revenue (continued)

Disaggregation of Revenue

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

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

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

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

16.
Related party transactions

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

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

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

17.
Stock-based compensation

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

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

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

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

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

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

17.
Stock-based compensation (continued)

A summary of option outstanding as of September 30, 2018 and December 31, 2017, and the changes during the three months ended March 31, 2018, June 30, 2018 and September 30, 2018, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding at December 31, 2017	21,593,385	$0.31
Granted	-	$-
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at March 31, 2018	21,593,385	$0.31
Granted	2,130,000	$0.41
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at June 30, 2018	23,723,385	$0.32
Granted	7,950,000	$0.21
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at September 30, 2018	31,673,385	$0.29
Vested and exercisable at September 30, 2018	31,673,385	$0.29

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

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

18.
Earnings (loss) per share

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

As a result of the net loss for the nine months ended September 30, 2018 and 2017, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive equity securities totaled 158,075,531 shares and 99,388,222 shares at September 30, 2018 and 2017, respectively.

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

19.
Subsequent events

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

Short term notes payable – related party

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

Consulting agreement

On October 17, 2018, the Company and a vendor agreed to settle a portion of a previously incurred fee for services in Common Stock in lieu of cash. On October 17, 2018, the Company issued 426,176 shares for services rendered May 2017 through February 2018. Non-cash general and administrative expense of $15,000 and $60,000 was recorded in 2018 and 2017, respectively.

Line of credit – related parties

On November 12, 2018, the Company entered into an amendment to the line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company. The line of credit was increased to $1,000,000 with an annualized interest rate of 6%. The line of credit may be called for payment upon demand of the holder. On October 5, 2018 and October 23, 2018, the Company received $15,000 and $40,000, respectively, as an increase in the line of credit.

Short term notes payable

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

Joint venture incorporated

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

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

Employment Agreement for Chief Financial Officer

On November 30, 2018, the Company entered into a Employee/Employer Agreement (the “Agreement”) with Kevin Richardson to be hired to serve as Chief Executive Officer of the Company effective November 30, 2018. Mr. Richardson will continue to serve as Chairman of the Board of Directors of the Company.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of SANUWAVE Health, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SANUWAVE Health, Inc. and Subsidiaries (the "Company") as of December 31, 2017 and 2016 and the related consolidated statements of comprehensive loss, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note (1) to the consolidated finacial statements, the Company has suffered recurring losses from operations and is dependent upon future issuances of equity or other financing to fund ongoing operations, both of which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are described in Note (1). The conolidated financial statements do not include any adjustments that might result for the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

CHERRY BEKAERT LLP

We have served as the Company's auditor since 2016.

Atlanta, Georgia
March 29, 2018

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2017 and 2016

	2017	2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$730,184	$133,571
Accounts receivable, net of allowance for doubtful accounts of $92,797 in 2017 and $35,196 in 2016	152,520	460,799
Inventory, net (Note 3)	231,532	231,953
Prepaid expenses	90,288	87,823
TOTAL CURRENT ASSETS	1,204,524	914,146
PROPERTY AND EQUIPMENT, net (Note 4)	60,369	76,938
OTHER ASSETS	13,917	13,786
TOTAL ASSETS	$1,278,810	$1,004,870
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$1,496,523	$712,964
Accrued expenses (Note 6)	673,600	375,088
Accrued employee compensation	1,680	64,860
Advances from related and unrelated parties (Note 7)	310,000	-
Line of credit, related parties (Note 8)	370,179	-
Convertible promissory notes, net (Note 9)	455,606	-
Interest payable, related parties (Note 10)	685,907	109,426
Short term loan, net (Note 11)	-	47,440
Warrant liability (Note 15)	1,943,883	1,242,120
Notes payable, related parties, net (Note 10)	5,222,259	5,364,572
TOTAL CURRENT LIABILITIES	11,159,637	7,916,470
TOTAL LIABILITIES	11,159,637	7,916,470
COMMITMENTS AND CONTINGENCIES (Note 16)		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 authorized; 6,175 shares issued and 0 shares outstanding in 2017 and 2016 (Note 14)	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001,		

293 authorized; 293 shares issued and 0 shares outstanding in 2017 and 2016, respectively (Note 14)	-	-
PREFERRED STOCK - UNDESIGNATED, par value $0.001, 4,993,532 shares authorized; no shares issued and outstanding (Note 14)	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 139,300,122 and 137,219,968 issued and outstanding in 2017 and 2016, respectively (Note 13)	139,300	137,220
ADDITIONAL PAID-IN CAPITAL	94,995,040	92,436,697
ACCUMULATED DEFICIT	(104,971,384)	(99,433,448)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(43,783)	(52,069)
TOTAL STOCKHOLDERS' DEFICIT	(9,880,827)	(6,911,600)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,278,810	$1,004,870

The accompanying notes to consolidated financial

statements are an integral part of these statements.

SANUWAVE
HEALTH, INC.
AND
SUBSIDIARIES

CONSOLIDATED
STATEMENTS OF
COMPREHENSIVE
LOSS

Years Ended
December 31, 2017
and 2016

	2017	2016
REVENUES	$738,527	$1,376,063
COST OF REVENUES (exclusive of depreciation and amortization shown below)	241,970	565,129
OPERATING EXPENSES		
Research and development	1,292,531	1,128,640
General and administrative	3,004,403	2,673,773
Depreciation	24,069	19,858
Amortization	-	306,756
Gain of sale of assets, property and equipment	-	(1,594)
TOTAL OPERATING EXPENSES	4,321,003	4,127,433
OPERATING LOSS	(3,824,446)	(3,316,499)
OTHER INCOME (EXPENSE)		
Loss on warrant valuation adjustment and conversion	(568,729)	(2,223,718)
Interest expense, net	(1,139,711)	(854,980)
Loss on foreign currency exchange	(5,050)	(12,329)
TOTAL OTHER INCOME (EXPENSE), NET	(1,713,490)	(3,122,541)
NET LOSS	(5,537,936)	(6,439,040)
OTHER COMPREHENSIVE INCOME (LOSS)		
Foreign currency translation adjustments	8,286	(18,907)
TOTAL COMPREHENSIVE LOSS	$(5,529,650)	$(6,457,947)

LOSS PER SHARE:		
Net loss - basic and diluted	$(0.04)	$(0.06)
Weighted average shares outstanding - basic and diluted	138,838,602	107,619,869

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Years Ended December 31, 2017 and 2016

	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 Income (Loss)	Total
Balances as of December 31, 2015	-	$-	63,056,519	$63,057	$87,086,677	$(92,994,408)	$(33,162)	$(5,877,836)
Net loss	-	-	-	-	-	(6,439,040)	-	(6,439,040)
Series A Warrant conversion to stock	293	-	7,447,954	7,447	880,971	-	-	888,418
Equity Offering	-	-	30,016,670	30,017	1,566,838	-	-	1,596,855
Preferred stock conversion	(293)	-	3,657,278	3,657	(3,657)	-	-	-
Peak One - Convertible Debenture	-	-	835,000	835	49,265	-	-	50,100
PIPE Offering	-	-	28,300,001	28,300	1,499,900	-	-	1,528,200

Warrant exercise	-	-	843,333	843	66,623	-	-	67,466
Cashless warrant conversion	-	-	2,627,821	2,628	263,093	-	-	265,721
Shares issued for services	-	-	435,392	436	43,104	-	-	43,540
Stock-based compensation - options	-	-	-	-	547,842	-	-	547,842
Beneficial conversion feature on debt	-	-	-	-	191,231	-	-	191,231
Warrants issued for services	-	-	-	-	186,410	-	-	186,410
Warrants issued with short term loan	-	-	-	-	58,400	-	-	58,400
Foreign currency translation adjustment	-	-	-	-	-	-	(18,907)	(18,907)
Balances as of December 31, 2016	-	-	137,219,968	137,220	92,436,697	(99,433,448)	(52,069)	(6,911,600)
Net loss	-	-	-	-	-	(5,537,936)	-	(5,537,936)
Warrant exercise	-	-	1,163,333	1,163	91,903	-	-	93,066
Cashless warrant exercise	-	-	866,625	867	66,100	-	-	66,967
Shares issued for services	-	-	50,196	50	7,950	-	-	8,000
Warrants issued for services	-	-	-	-	182,856	-	-	182,856
Stock-based compensation - options and warrants	-	-	-	-	768,105	-	-	768,105
Warrants issued with convertible promissory note	-	-	-	-	620,748	-	-	620,748
Beneficial conversion	-	-	-	-	820,681	-	-	820,681

feature on debt								
Foreign currency translation adjustment	-	-	-	-	-	-	8,286	8,286
Balances as of December 31, 2017	-	$-	139,300,122	$139,300	$94,995,040	$(104,971,384)	$(43,783)	$(9,880,827)

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

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SANUWAVE
HEALTH, INC.
AND
SUBSIDIARIES
CONSOLIDATED
STATEMENTS OF
CASH FLOWS
Years Ended
December 31, 2017
and 2016

	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(5,537,936)	$(6,439,040)
Adjustments to reconcile loss from continuing operations to net cash used by operating activities		
Amortization	-	306,756
Depreciation	24,069	19,858
Change in allowance for doubtful accounts	57,601	26,233
Stock-based compensation - employees, directors and advisors	768,105	547,842
Loss on warrant valuation adjustment	568,729	2,223,718
Amortization of debt issuance costs	431,087	225,786
Warrants issued for services	182,856	186,410
Amortization of debt discount	110,247	31,514
Stock issued for consulting services	8,000	43,540
Loss on conversion option of promissory notes payable	-	75,422
Stock issued with convertible debenture	-	50,100
Gain on sale of asset, property and equipment	-	(1,594)
Changes in assets - (increase)/decrease		
Accounts receivable - trade	250,678	(412,578)
Inventory	(7,079)	(29,249)
Prepaid expenses	(2,465)	36,165
Other	(131)	(2,689)
Changes in liabilities - increase/(decrease)		
Accounts payable	783,559	203,698
Accrued expenses	298,512	15,714
Accrued employee compensation	(63,180)	(176,682)
Accrued interest	21,896	-
Interest payable, related parties	576,481	(130,377)
NET CASH USED BY OPERATING ACTIVITIES	(1,528,971)	(3,199,453)
CASH FLOWS FROM INVESTING ACTIVITIES		

Proceeds from sale of property and equipment	-	1,594
Purchases of property and equipment	-	(10,364)
NET CASH USED BY INVESTING ACTIVITIES	-	(8,770)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from convertible promissory notes, net	1,384,232	106,000
Proceeds from line of credit, related party	370,000	-
Advances from related parties	310,000	-
Proceeds from warrant exercise	93,066	67,466
Proceeds from 2016 Public Offering, net	-	1,596,855
Proceeds from 2016 Private Offering, net	-	1,528,200
Proceeds from convertible debenture, net	-	175,000
Proceeds from short term loan	-	100,000
Payment of short term loan	(40,000)	-
Payment of convertible promissory notes	-	(155,750)
Payment of convertible debenture	-	(210,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,117,298	3,207,771
EFFECT OF EXCHANGE RATES ON CASH	8,286	(18,907)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	596,613	(19,359)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	133,571	152,930
CASH AND CASH EQUIVALENTS, END OF PERIOD	$730,184	$133,571
SUPPLEMENTAL INFORMATION		
Cash paid for interest, related parties	$-	$630,549
NONCASH INVESTING AND FINANCING ACTIVITIES		
Stock issued with convertible debenture	$-	$50,100
Stock issued for services	$8,000	$43,540
Loss on warrant conversion to stock	$-	$888,418
Beneficial conversion feature on convertible promissory notes	820,681	66,331
Beneficial conversion feature on convertible debenture	-	124,900
Beneficial conversion feature on convertible debt	$820,681	$191,231
Warrants issued for services	$182,856	$186,410
Warrants issued with convertible promissory note	$620,748	$-
Warrants issued for short tem loan	-	58,400
Warrants issued for debt	$620,748	$58,400

The accompanying notes to consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

1.
Going Concern

As shown in the accompanying consolidated financial statements, SANUWAVE Health, Inc. and Subsidiaries (the "Company") incurred a net loss of $5,537,936 and $6,439,040 during the years ended December 31, 2017 and 2016, respectively, and the net cash used by operating activities was $1,528,971 and $3,199,453, respectively. As of December 31, 2017, the Company had a net working capital deficit of $9,955,113, total stockholders' deficit of $9,880,827 and cash and cash equivalents of $730,184. These factors create an uncertainty about the Company's ability to continue as a going concern.

The Company does not currently generate significant recurring revenue and will require additional capital during the second quarter of 2018. Although no assurances can be given, management of the Company believes that existing capital resources should enable the Company to fund operations into the second quarter of 2018.

The continuation of the Company's business is dependent upon raising additional capital during the second quarter of 2018 and potentially into 2019 to fund operations. Management's plans are to obtain additional capital in 2018 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

2.
Summary of significant accounting policies

Description of the business – 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, 2018, the U.S. Food and Drug Administration (the "FDA") notified the Companyto permit the marketing of the dermaPACE System for the treatment of diabetic foot ulcers in the United States. In 2018, the Company plans to begin marketing its 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.

The significant accounting policies followed by the Company are summarized below:

Foreign currency translation - The functional currencies of the Company's foreign operations are the local currencies. The financial statements of the Company's foreign subsidiary have been translated into United States dollars in accordance with ASC 830, Foreign Currency Matters, Foreign Currency Translation. All balance sheet accounts have

been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. Translation adjustments are reported in other comprehensive loss in the consolidated statements of comprehensive loss and as cumulative translation adjustments in accumulated other comprehensive income (loss) in the consolidated statements of stockholders' deficit.

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

2.
Summary of significant accounting policies (continued)

Estimates – These consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. Because a precise determination of assets and liabilities, and correspondingly revenues and expenses, depend on future events, the preparation of consolidated financial statements for any period necessarily involves the use of estimates and assumptions. Actual amounts may differ from these estimates. These 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, estimated reserves for inventory, valuation of derivatives, accrued expenses, the determination of the valuation allowances for deferred taxes, estimated fair value of stock-based compensation, and estimated fair value of warrants and warrant liabilities.

Cash and cash equivalents - For purposes of the consolidated financial statements, liquid instruments with an original maturity of 90 days or less when purchased are considered cash and cash equivalents. The Company maintains its cash in bank accounts which may exceed federally insured limits.

Concentration of credit risk and limited suppliers - 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 8%, 38% and 24% of revenues for the year ended December 31, 2017, and 69%, 17% and 0% of accounts receivable at December 31, 2017. Two distributors accounted for 50% and 32% of revenues for the year ended December 31, 2016, and 87% and 10% of accounts receivable at December 31, 2016.

We depend on suppliers for product component materials and other components that are subject to stringent regulatory requirements. We currently purchase most of our product component materials from single suppliers and the loss of any of these suppliers could result in a disruption in our production. If this were to occur, it may be difficult to arrange a replacement supplier because certain of these materials may only be available from one or a limited number of sources. In addition, establishing additional or replacement suppliers for these materials may take a substantial period of time, as certain of these suppliers must be approved by regulatory authorities.

Accounts receivable - Accounts receivable are stated at the amount management expects to collect from outstanding balances. Management provides for probable uncollectible amounts through a charge to earnings based on its assessment of the current status of individual accounts. Receivables are generally considered past due if greater than 60 days old. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the allowance for doubtful accounts.

Inventory - Inventory consists of finished medical equipment and parts and is stated at the lower of cost or market, which is valued using the first in, first out ("FIFO") method. Market is based upon 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.

Depreciation of property and equipment - The straight-line method of depreciation is used for computing depreciation on property and equipment. Depreciation is based on estimated useful lives as follows: machines and equipment, 3 years; old or used devices, 5 years; new devices, 15 years; office and computer equipment, 3 years; furniture and

fixtures, 3 years; and software, 2 years.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

2.
Summary of significant accounting policies (continued)

Intangible assets - Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over 11.4 years. The Company regularly reviews intangible assets to determine if facts and circumstances indicate that the useful life is shorter than the Company originally estimated or that the carrying amount of the assets may not be recoverable. Factors the Company considers important and could trigger an impairment review include the following:

Significant changes in the manner in which the Company uses its assets or significant changes in the Company's overall business strategy; and

Significant underperformance of the Company's assets relative to future operating results.

If such facts and circumstances exist, the Company assesses the recoverability of the intangible assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If recognition of an impairment charge is necessary, it is measured as the amount by which the carrying amount of the intangible asset exceeds its fair value.

Fair value of financial instruments - The book values of accounts receivable, accounts payable, and other financial instruments approximate their fair values, principally because of the short-term maturities of these instruments.

The Company has adopted ASC 820-10, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value and requires disclosures about fair value measurements. The framework that is set forth in this standard is applicable to the fair value measurements where it is permitted or required under other accounting pronouncements.

The ASC 820-10 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 - Unobservable inputs that are not corroborated by market data, therefore requiring the Company to develop its own assumptions.

The Company accounts for derivative instruments under ASC 815, Accounting for Derivative Instruments and Hedging Activities, as amended and interpreted. ASC 815 requires that the Company recognize all derivatives on the balance sheet at fair value. The fair value of the warrant liability is determined based on a lattice solution, binomial approach pricing model, and includes the use of unobservable inputs such as the expected term, anticipated volatility and risk-free interest rate, and therefore is classified within level 3 of the fair value hierarchy.

The following table sets forth a summary of changes in the fair value of the derivative liability for the year ended December 31, 2017:

	Warrant Liability
Balance at December 31, 2016	$1,242,120
New issuances	200,000
Redemptions	(66,966)
Change in fair value	568,729
Balance at December 31, 2017	$1,943,883

The Company's notes payable, related parties had an aggregate outstanding principal balance of $5,222,259, net of $150,484 debt discount at December 31, 2017 and $5,364,572, net of $8,171 debt discount at December 31, 2016, respectively. Interest accrues on the notes at a rate of ten percent per annum, effective January 2, 2017 due to interest payments being in default. The fair value was determined using estimated future cash flows discounted at current rates, which is a Level 3 measurement. The estimated fair value of the Company's notes payable, related parties was $5,488,720 and $4,923,723 at December 31, 2017 and 2016, respectively.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

2.
Summary of significant accounting policies (continued)

Impairment of long-lived assets – The Company reviews long-lived assets for impairment whenever facts and circumstances indicate that the carrying amounts of the assets may not be recoverable. An impairment loss is recognized only if the carrying amount of the asset is not recoverable and exceeds its fair value. Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the asset's carrying value is not recoverable, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds its fair value. The Company determines fair value by using a combination of comparable market values and discounted cash flows, as appropriate.

Revenue recognition - Sales of medical devices, including related applicators, 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. The Company recognizes revenues on shipments to distributors in the same manner as with other customers. Fees from services performed are recognized when the service is performed. Fees for upfront distribution license agreements will be recognized as identified performance obligations are satisfied.

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs incurred have been recorded in cost of revenues.

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

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

The Company will recognize in income tax expense interest and penalties related to income tax matters. For the years ended December 31, 2017 and 2016, the Company did not have any amounts recorded for interest and penalties.

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

calculation of diluted net income (loss) per share. As a result of the net loss for the years ended December 31, 2017 and 2016, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. Anti-dilutive equity securities consists of the following at December 31, 2017 and 2016, respectively:

	2017	2016
Stock Options	21,593,385	16,203,385
Warrants	97,977,851	78,086,749
Warrants	14,641,190	-
Anti-dilutive equity securities	134,212,426	94,290,134

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

2.
Summary of significant accounting policies (continued)

Comprehensive income – ASC 220, Comprehensive Income, Reporting Comprehensive Income establishes standards for reporting comprehensive income (loss) and its components in a financial statement. Comprehensive income (loss) as defined includes all changes in equity (net assets) during a period from non-owner sources. The only source of other comprehensive income (loss) for the Company, which is excluded from net income (loss), is foreign currency translation adjustments.

Stock-based compensation - The Company uses the fair value method of accounting prescribed by ASC 718, Compensation – Stock Compensation, Accounting for Stock-Based Compensation for its employee stock option program. Under ASC 718, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the applicable vesting period of the stock award.

Research and development - Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to the Company's products in clinical development, such as payments to contract research organizations, consulting fees for FDA submissions, universities performing non-medical related research and insurance premiums for clinical studies and non-medical research. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs.

Liabilites related to warrants issued - The Company records certain common stock warrants issued at fair value and recognizes the change in the fair value of such warrants as a gain or loss, which is reported in the Other Income (Expense) section of the Consolidated Statements of Comprehensive Loss. The Company reports these warrants at fair value and classified as liabilities because they contain certain down-round provisions allowing for reduction of their exercise price. The fair value of these warrants is estimated using a binomial options pricing model.

Warrants related to debt issued - The Company records a warrant discount related to warrants issued with debt at fair value and recognizes the cost using the straight-line method over the term of the related debt as interest expense, which is reported in the Other Income (Expense) section of our Consolidated Statements of Comprehensive Loss. This warrant discount is reported as a reduction of the related debt liability.

Beneficial conversion feature on convertible debt - The Company records a beneficial conversion feature related to convertible debt at fair value and recognizes the cost using the straight-line method over the term of the related debt as interest expense, which is reported in the Other Income (Expense) section of our Consolidated Statements of Comprehensive Loss. The beneficial conversion feature is reported as a reduction of the related debt liability.

Recent pronouncements – New accounting pronouncements are issued by the Financial Standards Board ("FASB") or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may

be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective method, which requires the standard to be applied to each prior period presented, or (ii) a modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to the opening retained earnings in the period of adoption. In July 2015, the FASB confirmed a one-year delay in the effective date of ASU 2014-09, making the effective date for the Company the first quarter of fiscal 2018 instead of the previous effective date, which was the first quarter of fiscal 2017. This one year deferral was issued by the FASB in ASU 2015-14, Revenue from Contracts with Customers (Topic 606). The Company can elect to adopt the provisions of ASU 2014-09 for annual periods beginning after December 31, 2017, including interim periods within that reporting period. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company will adopt the standard effective January 1, 2018 and currently anticipates using the modified retrospective approach with a cumulative effect adjustment to opening retained earnings. The evaluation of our contracts is substantially complete and, based upon the results of our evaluation, we do not expect the application of the new standard to these contracts to have a material impact to our consolidated statements of comprehensive loss, balance sheets, or cash flows either at initial implementation or on an ongoing basis. We will be finalizing our assessment in advance of the filing of our first quarter 2018 Form 10-Q. The disclosures related to revenue recognition will be significantly expanded under the standard, specifically around the quantitative and qualitative information about performance obligations and disaggregation of revenue. The expanded disclosure requirements will be included in our first quarter 2018 Form 10-Q.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

2.
Summary of significant accounting policies (continued)

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

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

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

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

3.
Inventory

Inventory consists of the following at December 31, 2017 and 2016:

	2017	2016
Inventory - finished goods	$136,534	$218,592
Inventory - parts	167,613	89,621
Gross inventory	304,147	308,213
Provision for losses and obsolescence	(72,615)	(76,260)
Net inventory	$231,532	$231,953

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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4.
Property and equipment

Property and equipment consists of the following at December 31, 2017 and 2016:

	2017	2016
Machines and equipment	$240,295	$240,295
Office and computer equipment	156,860	156,860
Devices	89,704	82,204
Software	34,528	34,528
Furniture and fixtures	16,019	16,019
Other assets	2,259	2,259
Total	539,665	532,165
Accumulated depreciation	(479,296)	(455,227)
Net property and equipment	$60,369	$76,938

Depreciation expense was $24,069 and $19,858 for the years ended December 31, 2017 and 2016, respectively. The depreciation policies followed by the Company are described in Note 2.

5.
Intangible assets

Intangible assets consist of the following at December 31, 2017 and 2016:

	2017	2016
Patents, at cost	$3,502,135	$3,502,135
Less accumulated amortization	(3,502,135)	(3,502,135)
Net intangible assets	$-	$-

Amortization expense was $0 and $306,756 for the years ended December 31, 2017 and 2016, respectively. The amortization policies followed by the Company are described in Note 2.

6.
Accrued expenses

Accrued expenses consist of the following at December 31, 2017 and 2016:

	2017	2016
Accrued outside services	$165,427	$31,533
Accrued board of director's fees	125,000	16,000
Accrued executive severance	118,000	100,000
Accrued audit and tax preparation	73,800	100,000
Accrued legal professional fees	61,890	45,000
Deferred rent	51,191	41,341
Accrued travel	39,926	-
Accrued clinical study expenses	13,650	13,650
Deferred revenue	13,317	18,810
Accrued other	11,399	8,754
	$673,600	$375,088

On November 6, 2012, the Company entered into a Severance and Advisory Agreement (the “Severance Agreement”) with Christopher M. Cashman in connection with his resignation as President and Chief Executive Officer, and a director of the Company. Pursuant to the Severance Agreement, Mr. Cashman will receive, as severance along with other non-cash items, six months of his base salary payable over the following six month period and bonus payments of $100,000 upon each of four bonus payment events tied to the Company’s clinical trial plan for the dermaPACE device, or December 31, 2016, whichever occurs first. The Company achieved three of the four bonus payment events in 2014 and paid $300,000 in accrued executive severance during the year ended December 31, 2014. The accrued executive severance at December 31, 2017 represents the unpaid portion of the bonus payments plus accrued interest due to late payment and the accrued executive severance at December 31, 2016 represents the unpaid portion of the bonus payments.

On May 1, 2017, the Company entered into an agreement with an investment company to provide business advisory and consulting services. The compensation for those services was to be paid in a combination of cash and Company common stock. At December 31, 2017, the Company accrued $120,000 of expense for the services provided. The common stock was issued in March 2018 in the amount of 467,423 shares.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2017 and 2016

7.
Advances from related and unrelated parties

The Company has received cash advances from related parties and accredited investors to help fund the Company's operations. These advances are a part of an agreement that the Company is offering to issue convertible promissory notes. As of December 31, 2017, the Company had received $310,000 from related parties and accredited investors. A. Michael Stolarski and Kevin A. Richardson II, both members of the Company's board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The convertible promissory notes for this balance were issued on January 10, 2018 (see Note 20).

8.
Line of credit, related parties

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

Interest expense on line of credit, related parties totaled $179 and $0 for the years ended December 31, 2017 and 2016, respectively.

9.
Convertible promissory notes

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

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

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

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

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

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

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

Interest expense on the 10% Convertible Promissory Notes totaled $452,804 for the year ended December 31, 2017.

A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $330,000 and was issued 3,000,000 Class N Warrants.

10.
Notes payable, related parties

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

On June 15, 2015, the Company and HealthTronics, Inc. entered into an amendment (the "Note Amendment") to amend certain provisions of the notes payable, related parties. The Note Amendment provides for the extension of the due date to January 31, 2017. In connection with the Note Amendment, the Company entered into a security agreement with HealthTronics, Inc. to provide a first security interest in the assets of the Company. The notes payable, related parties bear interest at 8% per annum effective August 1, 2015 and during any period when an Event of Default occurs, the applicable interest rate shall increase by 2% per annum. Events of Default under the notes payable, related parties have occurred and are continuing on account of the failure of SANUWAVE, Inc., a Delaware corporation, a wholly owned subsidiary of the Company and the borrower under the notes payable, related parties, to make the required payments of interest which were due on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017, and December 31, 2017 (collectively, the "Defaults"). As a result of the Defaults, the notes payable, related parties have been accruing interest at the rate of 10% per annum since January 2, 2017 and continue to accrue interest at such rate. The Company will be required to make mandatory prepayments of principal on the notes payable, related parties equal to 20% of the proceeds received by the Company through the issuance or sale of any equity securities in cash or through the licensing of the Company's patents or other intellectual property rights.

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

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

The notes payable, related parties had an aggregate outstanding principal balance of $5,222,259, net of $150,484 debt discount at December 31, 2017 and $5,364,572, net of $8,171 debt discount at December 31, 2016, respectively.

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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10.
Notes payable, related parties (continued)

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

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

Accrued interest currently payable totaled $685,907 and $109,426 at December 31, 2017 and 2016, respectively.

As of January 1, 2017, we are in default with our interest payment and the note is callable by HealthTronics, Inc. The notes payable, related parties are shown as a current liability.

Maturities on notes payable, related parties are as follows:

Years ending December 31,	Amount
2018	$5,372,743
Total	$5,372,743

Interest expense on notes payable, related parties totaled $634,169 and $541,982 for the years ended December 31, 2017 and 2016, respectively.

11.
Short term loan

On December 21, 2016, the Company entered into a short term loan with Millennium Park Capital LLC (the "Holder") in the principal amount of $100,000. The principal amount shall be due and payable on March 31, 2017, the date that money is obtained from the Company's Korean distributor, or the date that money is obtained from a new distributor.

In addition, the Company will issue to the Holder 500,000 warrants to purchase shares of Common Stock, at an exercise price of $0.17. Each warrant will represent the right to purchase one share of Common Stock. The warrants will vest upon issuance and have an expiration date of March 17, 2019. The fair value of these warrants on the date of issuance $0.1168, using the Black-Scholes option pricing model, and $58,400 was recorded as a debt discount to be amortized over the life of the short term loan. The Company issued the Holder 500,000 warrants to purchase shares of

the Company's common stock at an exercise price of $0.11 on November 30, 2017. The warrants will vest upon issuance and have an expiration date of March 17, 2019. The estimated fair value of these warrants on the date of issuance at the new exercise price was $10,662 and was recorded as an increase to additional paid-in capital.

On November 30, 2017, the outstanding balance of $60,000 was converted into the 10% Convertible Promissory Notes (see Note 9).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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12.
Income taxes

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

Deferred income taxes are provided for temporary differences between the carrying amounts and tax basis of assets and liabilities. Deferred taxes are classified as current or noncurrent based on the financial statement classification of the related asset or liability giving rise to the temporary difference. For those deferred tax assets or liabilities (such as the tax effect of the net operating loss carryforwards) which do not relate to a financial statement asset or liability, the classification is based on the expected reversal date of the temporary difference.

The income tax provision (benefit) from continuing operations consists of the following at December 31, 2017 and 2016:

	2017	2016
Current:		
Federal	$-	$-
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	8,371,516	(1,367,488)
State	1,489,172	(150,246)
Foreign	(19,224)	7,128
Change in valuation allowance	(9,841,464)	1,510,606
	$-	$-

On December 22, 2017, H.R. 1, commonly known as the Tax Cuts and Jobs Act (the “Act”) was signed into law. The Act reduced the Company’s corporate federal tax rate from 35% to 21% effective January 1, 2018 and changed certain other provisions. As a result, the Company is required to re-measure the deferred tax assets and liabilities using the enacted rate at which they expect them to be recovered or settled. The effect of this re-measurement is recorded to income tax expense in the year the tax law is enacted. For 2017, the re-measurement of our net deferred tax asset resulted in a $11.1 million adjustment to the income tax provision (benefit) at December 31, 2017.

The income tax provision (benefit) amounts differ from the amounts computed by applying the United States federal statutory income tax rate of 35% for the years ended December 31, 2017 and 2016 to pretax income (loss) from continuing operations as a result of the following for the years ended December 31, 2017 and 2016:

	2017	2016
Tax benefit at statutory rate	$(1,938,278)	$(2,253,664)
Increase (reduction) in income taxes resulting from:		
State income benefit, net of federal benefit	(136,538)	(160,335)
Non-deductible loss on warrant valuation adjustment	199,055	665,719
Income (loss) from foreign subsidiaries	(34,552)	17,077
Change in valuation allowance - United States	(9,841,464)	1,510,606
Tax reform rate adjustment	11,827,143	-
Other	(75,366)	220,597
Income tax expense (benefit)	$-	$-

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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12.
Income taxes (continued)

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2017 and 2016 are as follows:

	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$19,406,373	$27,839,703
Net operating loss carryforwards - foreign	139,675	120,451
Excess of tax basis over book value of property and equipment	6,978	13,933
Excess of tax basis over book value of intangible assets	220,180	447,626
Stock-based compensation	906,526	2,038,638
Accrued employee compensation	-	24,030
Captialized equity costs	49,471	75,471
Inventory reserve	17,962	28,777
	20,747,165	30,588,629
Valuation allowance	(20,747,165)	(30,588,629)
Net deferred tax assets	$-	$-

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

The federal net operating loss carryforwards at December 31, 2017 will begin to expire in 2025.

13.
Equity Transactions

Warrant Exercise

For the year ended December 31, 2017, the Company issued 1,163,333 shares of common stock upon the exercise of 1,163,333 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L Warrant agreement.

For the year ended December 31, 2016, the Company issued 843,333 shares of common stock upon the exercise of 843,333 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L Warrant agreement.

Cashless Warrant Exercise

For the year ended December 31, 2017, the Company issued 447,118 shares of common stock upon the cashless exercise of 883,499 Class L Warrants to purchase shares of stock for $0.08 per share based on the current market value per share as of the date of conversion as determined under the terms of the Class L Warrant agreement.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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13.
Equity Transactions (continued)

For the year ended December 31, 2017, the Company issued 419,507 shares of common stock upon the cashless exercise of 545,246 Series A Warrants to purchase shares of stock for $0.0334 per share based on the current market value per share as of the date of conversion as determined under the terms of the Series A Warrant agreement.

For the year ended December 31, 2016, the Company issued 117,510 shares of common stock upon the cashless exercise of 143,400 Series A Warrants to purchase shares of stock for $0.0334 per share based on the current market value per share as of the date of conversion as determined under the terms of the Series A Warrant agreement.

For the year ended December 31, 2016, the Company issued 869,722 shares of common stock upon the cashless exercise of 1,943,334 Class M Warrants to purchase shares of stock for $0.06 per share based on the current market value per share as of the date of conversion as determined under the terms of the Class M Warrant agreement.

For the year ended December 31, 2016, the Company issued 1,640,589 shares of common stock upon the cashless exercise of 4,641,667 Class J Warrants to purchase shares of stock for $0.06 per share based on a current market value per share as of the date of conversion as determined under the terms of the Class J Warrant agreement.

2016 Private Placement

On August 11, 2016, the Company began a private placement of securities (the “2016 Private Placement”) with select accredited investors in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), an Rule 506 of Regulation D (“Regulation D”) as promulgated by the United States Securities and Exchange Commission (the “Commission”) under the Securities Act. The 2016 Private Placement offered Units (the “Units”) at a purchase price of $0.06 per Unit, with each Unit consisting of (i) one (1) share of our Common Stock and, (ii) one (1) detachable warrant (the “Warrants”) to purchase one (1) share of our Common Stock at an exercise price of $0.08 per share.

On August 25, 2016 and September 27, 2016 in conjunction with the 2016 Private Placement, the Company issued an aggregate of 22,766,667 and 5,533,334, respectively, shares of common stock for an aggregate purchase price of $1,366,000 and $332,000, respectively.

The Company, in connection with the 2016 Private Placement, issued to the investors an aggregate of 28,300,001 warrants (the “Class L Warrants”) to purchase shares of common stock at an exercise price of $0.08 per share. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019.

Pursuant to the terms of a Registration Rights Agreement that the Company entered with the accredited investors in connection with the 2016 Private Placement, the Company is required to file a registration statement that covers the shares of Common Stock and the shares of common stock issuable upon exercise of the Warrants. The failure on the part of the Company to satisfy certain deadlines described in the Registration Rights Agreement may subject the Company to payment of certain monetary penalties.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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13.
Equity Transactions (continued)

Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Private Placement of $75,000. A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Private Placement of $60,000.

At the closing of the 2016 Private Placement, the Company paid West Park Capital, Inc., the placement agent for the equity offering, cash compensation of $169,800 based on the gross proceeds of the private placement and 2,830,000 Class L Warrants.

Consulting Agreement

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

In August 2016, the Company entered into a consulting agreement for which the fee for the services performed was paid with Common Stock. The Company issued 435,392 shares of Common Stock to Vigere Capital LP under this agreement. The fair value of the Common Stock issued to the consultant, based upon the closing market price of the Common Stock at the date the Common Stock was issued, was recorded as a non-cash general and administrative expense for the year ended December 31, 2016.

Convertible Debenture and Restricted Stock

On July 29, 2016, the Company entered into a financing transaction for the sale of a Convertible Debenture (the "Debenture") in the principal amount of $200,000, with proceeds of $175,000 to the Company after payment of a 10% original issue discount. The offering was conducted pursuant to the exemption from registration provided by Section 4(a)(2) of the Act and Rule 506 of Regulation D thereunder. The Company did not utilize any form of general solicitation or general advertising in connection with the offering. The Debenture was offered and sold to one accredited investor (the "Investor").

The Investor is entitled to, at any time or from time to time, commencing on the date that is one hundred fifty one (151) days from the issuance date set forth above convert the conversion amount into conversion shares, at a conversion price for each share of common stock equal to either (i) if the Company is Deposit/Withdrawal at Custodian ("DWAC") operational at the time of conversion, seventy percent (70%) of the lowest closing bid price (as reported by Bloomberg LP) of common stock for the twenty (20) trading days immediately preceding the date of the date of conversion of the Debentures, or (ii) if either the Company is not DWAC operational or the common stock is traded on the bottom tier over-the-counter Pink (or, "pink sheets") at the time of conversion, sixty five percent (65%) of the lowest closing bid price (as reported by Bloomberg LP) of the common stock for the twenty (20) trading days immediately preceding the date of conversion of the Debentures, subject in each case to equitable adjustments

resulting from any stock splits, stock dividends, recapitalizations or similar events.

The Company recorded $124,900 in interest expense for the beneficial conversion feature of the debenture in December 2016.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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13.
Equity Transactions (continued)

The Debenture is secured by the accounts receivable of the Company and, unless earlier redeemed, matures on the third anniversary date of issuance. The Company paid a commitment fee of of $2,500 and issued 835,000 shares of restricted stock. The fair value of the restricted stock on the date of issuance was $0.06 per share and $50,100 was recorded as interest expense in July 2016.

In September 2016, the Company repaid the Debenture in full which totaled $210,000 with a Redemption Price of 105% of the sum of the Principal Amount per the agreement. The premium of $10,000 paid upon redemption was recorded as interest expense in September 2016.

2016 Equity Offering

On March 11, 2016, April 6, 2016, and April 15, 2016 in conjunction with an equity offering of securities (the "2016 Equity Offering") with select accredited investors, the Company issued an aggregate of 25,495,835, 3,083,334 and 1,437,501, respectively, shares of common stock for an aggregate purchase price of $1,529,750, $185,000, and $86,200, respectively. The mandatory prepayment of principal on the Notes payable, related parties equal to 20% of the proceeds received by the Company required by the Note Amendment on June 15, 2015 was waived by HealthTronics, Inc. for this 2016 Equity Offering.

The Company, in connection with the 2016 Equity Offering, issued to the investors an aggregate of 30,016,670 warrants (the "Class L Warrants") to purchase shares of common stock at an exercise price of $0.08 per share. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019.

Pursuant to the terms of a Registration Rights Agreement that the Company entered into with the investors in connection with the 2016 Equity Offering, the Company is required to file a registration statement that covers the shares of common stock and the shares of common stock issuable upon exercise of the Class L Warrants. The registration statement was declared effective by the SEC on February 16, 2016.

Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Equity Offering of $100,000. A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company, was a purchaser in the 2016 Equity Offering of $75,000.

At the closing of the 2016 Equity Offering, the Company paid Newport Coast Securities, Inc., the placement agent for the equity offering, cash compensation of $180,095 based on the gross proceeds of the private placement and 3,001,667 Class L Warrants. In addition, the Company paid an escrow fee of $4,000 and an attorney fee of $20,000 from the gross proceeds.

Series A Warrant Conversion

On January 13, 2016, the Company entered into an Exchange Agreement (the "Exchange Agreement") with certain beneficial owners (the "Investors") of Series A warrants (the "Warrants") to purchase shares of Common Stock, pursuant

to which the Investors exchanged (the “Exchange”) all of their respective Warrants for either (i) shares of Common Stock or (ii) shares of Common Stock and shares of the Company’s Series B Convertible Preferred Stock, $0.001 par value (the “Preferred Stock”).

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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13.
Equity Transactions (continued)

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

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

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

14.
Preferred Stock

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

Under the Certificate of Designation, holders of Series B Convertible Preferred Stock are entitled to receive dividends equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. Such holders will participate on an equal basis per-share with holders of common stock in any distribution upon winding up, dissolution, or liquidation of the Company. Holders of Series B Convertible Preferred Stock are entitled to convert

each share of Series A Convertible Preferred Stock into 2,000 shares of common stock, provided that after giving effect to such conversion, such holder, together with its affiliates, shall not beneficially own in excess of 9.99% of the number of shares of common stock outstanding (the “Beneficial Ownership Limitation”). Holders of the Series B Convertible Preferred Stock are entitled to vote on all matters affecting the holders of the common stock on an “as converted” basis, provided that such holder shall only vote such shares of Series B Convertible Preferred Stock eligible for conversion without exceeding the Beneficial Ownership Limitation.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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14.
Preferred Stock (continued)

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

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

15.
Warrants

A summary of warrants as of December 31, 2017 and 2016, and the changes during the years ended December 31, 2017 and 2016, is presented as follows:

Warrant class	Outstanding as of December 31, 2015	Issued	Exercised	Converted	Expired	Outstanding as of December 31, 2016	Issued	Exercised	Out as o Dec 31, 2017
Class E Warrants	3,576,737	-	-	-	(3,576,737)	-	-	-	-
Class F Warrants	300,000	-	-	-	-	300,000	-	-	300
Class G Warrants	1,503,409	-	-	-	-	1,503,409	-	-	1,5
Class H Warrants	1,988,095	-	-	-	-	1,988,095	-	-	1,9

Class I Warrants	1,043,646	-	-	-	-	1,043,646	-	-	1,0
Class J Warrants	629,378	4,012,289	(4,641,667)	-	-	-	-	-	-
Class K Warrants	3,310,000	1,890,000	-	-	-	5,200,000	2,000,000	-	7,2
Class L Warrants	-	66,788,338	(843,333)	-	-	65,945,005	-	(2,046,832)	63,
Class M Warrants	-	1,943,333	(1,943,333)	-	-	-	-	-	-
Class N Warrants	-	-	-	-	-	-	13,943,180	-	13,
Class O Warrants	-	-	-	-	-	-	6,540,000	-	6,5
Series A Warrants	25,951,421	-	(143,400)	(23,701,427)	-	2,106,594	-	(545,246)	1,5
	38,302,686	74,633,960	(7,571,733)	(23,701,427)	(3,576,737)	78,086,749	22,483,180	(2,592,078)	97,

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

	Exercise price/share	Expiration date
Class F Warrants	$0.35	February 2018
Class G Warrants	$0.80	July 2018
Class H Warrants	$0.80	July 2018
Class I Warrants	$0.85	September 2018
Class K Warrants	$0.08	June 2025
Class K Warrants	$0.11	August 2027
Class L Warrants	$0.08	March 2019
Class N Warrants	$0.11	March 2019
Class O Warrants	$0.11	March 2019
Series A Warrants	$0.03	March 2019

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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15.
Warrants (continued)

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

The exercise price of the Class 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 securities at a price lower than the then applicable exercise price of the warrants. 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 if effective. If a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale by the holder of the Series A Warrants, then the holder may exercise the warrants on a cashless basis.

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

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

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

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

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

On December 11, 2017, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000

shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $285,810 and was recorded as research and development expense in the amount of $98,655 and general and administrative expense in the amout of $187,155 and an increase to additional paid-in capital for the full amount of $285,810. The warrants vested upon issuance and expire on March 17, 2019. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company's board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company's board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants.

The fair value of each Class O Warrant Agreement grant is estimated on the date of grant using the BlackScholes option pricing model using the following assumptions for the year ended December 31, 2017:

	2017
Expected life in years	1.26 - 1.29
Risk free interest rate	1.70% - 1.76%
Volatility	88.06% - 90.00%
Forfeiture rate	0.0%
Expected dividend yield	0.0%

The Class K Warrants, the Series A Warrants and the Series B Warrants are classified as derivative financial instruments. The estimated fair values of the Class K Warrants at the dates of grant were $36,989 on June 15, 2015, $9,214 on June 28, 2016, and $200,000 on August 3, 2017. These amounts were recorded as debt discount, which is accreted to interest expense through the amended maturity dates 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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15.
Warrants (continued)

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

The fair value of the derivative classified warrants is estimated using the binomial option pricing model using the following assumptions for the year endeds December 31, 2017 and 2016:

	2017	2016
Expected life in years	1.21 - 9.60	2.20 - 8.50
Risk free interest rate	1.79% - 2.39%	1.25% - 2.35%
Volatility	109.00% - 133.00%	150.00%
Forfeiture rate	0.0%	0.0%
Expected dividend yield	0.0%	0.0%

A summary of the changes in the warrant liability as of December 31, 2017 and December 31, 2016, and the changes during the years ended December 31, 2017 and 2016, is presented as follows:

	Class J Warrants	Class K Warrants	Class M Warrants	Series A Warrants	Total
Warrant liability as of December 31, 2015	$2,900	$22,700	$-	$112,500	$138,100
Issued	-	25,350	9,091	-	34,441
Redeemed	(153,175)	-	(114,492	(886,472)	(1,154,139)
Change in fair value	150,275	835,950	105,401	1,132,092	2,223,718
Warrant liability as of December 31, 2016	$-	$884,000	$-	$358,120	$1,242,120
Issued	-	200,000	-	-	200,000
Redeemed	-	-	-	(66,966)	(66,966)

Change in fair value	-	532,000	-	36,729	568,729
Warrant liability as of December 31, 2017	$-	$1,616,000	$-	$327,883	$1,943,883

16.
Commitments and contingencies

Operating Leases

The Company leases office and storage space. Rent expense for the years ended December 31, 2017 and 2016, was $159,583 and $178,073, respectively. Minimum future lease payments under the operating lease consist of the following:

Year ending December 31,	Amount
2018	$138,861
2019	143,318
2020	147,617
2021	152,046
Total	$581,842

Litigation

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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17.
Stock-based compensation

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Stock Incentive Plan"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is currently administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to three years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At December 31, 2017 and 2016, the Stock Incentive Plan reserved a total of 22,500,000 shares of common stock for grant.

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

On November 9, 2016, the Company granted to the active employees, members of the board of directors and two members of the Company's Medical Advisory Board options to purchase 2,830,000 shares each of the Company's common stock at an exercise price of $0.18 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.1524 per option resulting in compensation expense of $431,292. Compensation cost was recognized upon grant.

On June 16, 2016, the Company granted to the active employees, members of the board of directors and two members of the Company's Medical Advisory Board options to purchase 3,300,000 shares each of the Company's common stock at an exercise price of $0.04 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.0335 per option resulting in compensation expense of $110,550. Compensation cost was recognized upon grant.

On October 1, 2015, the Company granted to the active employees and members of the board of directors options to purchase 1,900,000 shares of common stock at an exercise price of $0.11 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.11 resulting in compensation expense of $209,000. Compensation cost was recognized upon grant.

On October 1, 2015, the Company granted to the active employees, members of the board of directors and members of the Medical Advisory Board options to purchase 1,450,000 shares of common stock an exercise price of $0.50 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.10 resulting in compensation expense of $145,000. Compensation cost was recognized upon grant.

On August 13, 2015, Mr. Chiarelli and the Company entered into a confidential settlement agreement in response to an action filed against the Company by Mr. Chiarelli. The settlement agreement contains the entire understanding and complete agreement of the parties involved with respect to the circumstances, matters, events and transactions that were a subject of the action. A part of the settlement was the issuance of stock options. Using the Black-Scholes option pricing model, management has determined that the options had a fair value resulting in compensation expense of $98,100. Compensation cost was recognized upon grant.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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17.
Stock-based compensation (continued)

On April 28, 2015, the Company granted two members of the Company's Medical Advisory Board each options to purchase 50,000 shares of the Company's common stock at an exercise price of $0.55 per share in place of an annual cash consulting fee for calendar year 2015. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.11 resulting in compensation expense of $11,107. Compensation cost was recognized over the requisite service period in calendar year 2015.

On May 7, 2014, the Company granted to the active employees options to purchase 900,000 shares of common stock at an exercise price of $0.55 per share. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.48 resulting in total compensation expense of $429,001 that was recognized over the three year vesting period of the options. Compensation expense related to this grant was $6,000 and $30,000 for the years ended December 31, 2016 and 2015, respectively.

On February 21, 2013, the Company, granted the active employees and directors options to purchase 2,243,644 shares of common stock at an exercise price of $0.35 per share. Using the Black-Scholes option pricing model, management has determined that the options had an average fair value per share of $0.223 resulting in total compensation of $499,621. Compensation cost is being recognized over the requisite service period. Compensation expense related to this grant was $0 and $11,327 for the years ended December 31, 2016 and 2015, respectively.

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

	2017	2016
Weighted average expected life in years	5.0	5.0
Weighted average risk free interest rate	1.76%	1.28%
Weighted average volatility	120.00%	133.54%
Forfeiture rate	0.0%	0.0%
Expected dividend yield	0.0%	0.0%

The expected life of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted. The risk-free rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of the grant. The expected volatility is based on the average volatility of the Company and that of peer group companies similar in size and value to us. We estimate pre-vesting forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The expected dividend yield is based on our historical dividend experience, however, since our inception, we have not declared dividends. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest.

For the years ended December 31, 2017 and 2016, the Company recognized $482,295 and $547,842, respectively, as compensation cost related to options granted. As of December 31, 2017, there are no unamortized compensation costs related to options granted.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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17.
Stock-based compensation (continued)

A summary of option activity as of December 31, 2017 and 2016, and the changes during the years ended December 31, 2017 and 2016, is presented as follows:

	Options	Weighted Average Exercise Price per share
Outstanding at December 31, 2015	10,073,385	$0.62
Granted	6,130,000	$0.10
Exercised	-	$-
Forfeited or expired	-	$-
Outstanding at December 31, 2016	16,203,385	$0.38
Granted	5,550,000	$0.11
Exercised	-	$-
Forfeited or expired	(160,000)	$0.22
Outstanding at December 31, 2017	21,593,385	$0.31
Vested and exercisable at December 31, 2017	21,593,382	$0.31

The range of exercise prices for options was $0.04 to $2.00 for options outstanding at December 31, 2017 and 2016, respectively. The aggregate intrinsic value for outstanding options was $2,073,641 and $702,500 at December 31, 2017 and 2016, respectively. The aggregate intrinsic value for all vested and exercisable options was $2,073,641 and $702,500 at December 31, 2017 and 2016, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options is 7.37 years and 5.88 years as of December 31, 2017 and 2016, respectively.

A summary of the Company’s nonvested options as of December 31, 2017 and 2016, and changes during the years ended December 31, 2017 and 2016, is presented as follows:

Weighted

	Options	Average Exercise Price per share
Outstanding at December 31, 2015	175,002	$0.36
Granted	6,130,000	$0.10
Vested	(6,305,002)	$0.11
Forfeited or expired	-	$-
Outstanding at December 31, 2016	-	$-
Granted	5,550,000	$0.11
Vested	(5,550,000)	$0.11
Forfeited or expired	-	$-
Outstanding at December 31, 2017	-	$-

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
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18.
Joint venture

On September 27, 2017, the Company entered into a binding term sheet with MundiMed Distribuidora Hospitalar LTDA ("MundiMed"), effective as of September 25, 2017, pursuant to which the Company and MundiMed will enter into a joint venture for the manufacture, sale and distribution of the Company's dermaPACE device. The binding term sheet provides that the parties will work together to enter into a definitive agreement reflecting the binding term sheet terms, but that to the extent a definitive agreement has not been executed by the parties by September 30, 2017, the terms set forth in the binding term sheet shall be binding.

Under the binding term sheet, MundiMed will pay the Company an upfront distibution fee on September 30, 2017, which fee was received on October 6, 2017, with monthly upfront distibution fees payable thereafter over the following eighteen months. MundiMed bears the cost of any and all fees and expenses incurred in connection with the formation, organization and start-up of the joint venture, which fees and expenses are expected not to exceed $200,000. Profits from the joint venture are distributed as follows: 45% to the Company, 45% to MundiMed and 5% each to LHS Latina Health Solutions Gestão Empresarial Ltda. and Universus Global Advisors LLC, who acted as advisors in the transaction.

The binding term sheet terminates upon the earlier of (1) the date a definitive agreement evidencing the terms of the binding term sheet is executed by the parties and (2) May 30, 2019.

19.
Segment and geographic information

The Company has one line of business with revenues being generated from sales in Europe, Canada, Asia and Asia/Pacific. All significant expenses are generated in the United States. All significant assets are located in the United States.

20.
Subsequent events

10% Convertible Promissory Notes

A subsequent offering of the 10% Convertible Promissory Notes was closed on January 10, 2018, at which time $1,496,000 aggregate principal amount of 10% Convertible Promissory Notes were issued with $1,066,000 of funds paid to the Company. The remaining $430,000 of principal came from advances from related and unrelated parties balance at December 31, 2017 of $310,000 (see Note 7) and conversion of $120,000 of unpaid executive compensation by related party, Kevin A. Richardson II. On January 10, 2018, the Company issued 13,599,999 Class N Warrants in connection with such subsequent closing.

The final offering of the 10% Convertible Promissory Notes was closed on February 2, 2018, at which time $100,000 aggregate principal amount of 10% Convertible Promissory Notes were issued and the funds paid to the Company. On February 2, 2018, the Company issued 909,091 Class N Warrants in connection with such final closing.

Convertible Promissory Note

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

The Convertible Promissory Note has a six month term from the subscription date and the note holders can convert the Convertible Promissory Note at any time during the term to the number of shares of Company 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.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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20.
Subsequent events (continued)

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

Warrant Exercise

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

On March 28, 2018, the Company issued 75,666 shares of restricted common stock upon the exercise of 75,666 Series A Warrants to purchase shares of stock for $0.0334 per share under the terms of teh Series A Warrant agreement.

Cashless Warrant Exercise

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

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

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

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

Consulting Agreement

In November 2017, the Company entered into a three month consulting agreement for which a portion of the fee for the services was to be paid with Company common stock. The number of shares to be paid with Company common stock was calculated by dividing the amount of the fee to be paid with Company common stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 18,182 shares on January 9, 2018, for the third month of the agreement. The $4,000 was recorded as a non-cash general and administrative expense for each of the first two months of the agreement.

New Agreements

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

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

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

The following table lists the costs and expenses payable by the registrant in connection with the sale of the common stock covered by this prospectus. All amounts shown are estimates except for the SEC registration fee.

SEC registration fee	$1,760
Legal fees and expenses	30,000
Accounting fees and expenses	15,000
Total	$46,760

ITEM 14. Indemnification of Directors and Officers

The Nevada General Corporation Law (“NGCL”) provides that a director or officer is not individually liable to the corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his capacity as a director or officer unless (i) such act or omission constituted a breach of his/her fiduciary duties as a director or officer, and (ii) his/her breach of those duties involved intentional misconduct, fraud or a knowing violation of law. Under the NGCL, a corporation may indemnify directors and officers, as well as other employees and individuals, against any threatened, pending or completed action, suit or proceeding, except an action by or in the right of the corporation, by reason of the fact that he/she is or was a director, officer, employee or agent of the corporation so long as such person acted in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his/her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, does not, of itself, create a presumption that the person did not act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he/she had reasonable cause to believe that his/her conduct was unlawful.

The NGCL further provides that indemnification may not be made for any claim as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that, in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper. To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding or in defense of any claim, issue or matter therein, the corporation must indemnify him/her against expenses, including attorney’s fees, actually and reasonably incurred in connection with the defense. The NGCL provides that this is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders, or disinterested directors or otherwise.

The registrants articles of incorporation provide that the directors and officers will not be personally liable to the registrant or its stockholders for monetary damages for breach of their fiduciary duty as a director or officer, except for liability of a director or officer for acts or omissions involving intentional misconduct, fraud or a knowing violation of law, or the payment of dividends in violation of the NGCL. The registrant's bylaws and contractual arrangements with certain of its directors and officers provide that the registrant is required to indemnify its directors and officers to the fullest extent permitted by law. The registrant's bylaws and these contractual arrangements also require the registrant to advance expenses incurred by a director or officer in connection with the defense of any proceeding upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is

ultimately determined by a court of competent jurisdiction that he/she is not entitled to be indemnified by the registrant. The registrant's bylaws also permit the registrant to purchase and maintain errors and omissions insurance on behalf of any director or officer for any liability arising out of his/her actions in a representative capacity. The registrant does not presently maintain any such errors and omissions insurance for the benefit of its directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed hereby in the Securities Act and we will be governed by the final adjudication of such issue.

ITEM 15. Recent Sales of Unregistered Securities

In connection with each of the following unregistered sales and issuances of securities, except as otherwise provided below, the Company relied upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

Restricted Stock Issued Upon Warrant Exercises for Cash

On September 20, 2016, the Company issued 400,000 shares of restricted Common Stock upon the exercise of 400,000 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $32,000.

On October 14, 2016, the Company issued 258,333 shares of restricted Common Stock upon the exercise of 258,333 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $20,667.

On October 20, 2016, the Company issued 185,000 shares of restricted Common Stock upon the exercise of 185,000 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $14,800.

On January 24, 2017, the Company issued 600,000 shares of restricted Common Stock upon the exercise of 600,000 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $48,000.

On March 10, 2017, the Company issued 363,333 shares of restricted Common Stock upon the exercise of 363,333 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $29,067.

On April 3, 2017, the Company issued 100,000 shares of restricted Common Stock upon the exercise of 100,000 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $8,000.

On April 25, 2017, the Company issued 100,000 shares of restricted Common Stock upon the exercise of 100,000 Class L Warrants to purchase shares of stock for $0.08 per share under the terms of the Class L warrant agreement, for cash consideration of $8,000.

On February 23, 2018, the Company issued 100,000 shares of Common Stock upon the exercise of 100,000 Class O Warrants to purchase shares of stock for $0.11 per share under the terms of the Class O warrant agreement, for cash consideration of $11,000.

On March 23, 2018, the Company issued 75,666 shares of restricted Common Stock upon the exercise of 75,666 Series A Warrants to purchase shares of stock for $0.0334 per share under the terms of the Series A warrant agreement, for cash consideration of $2,527.

On April 20, 2018, the Company issued 227,273 shares of restricted Common Stock upon the exercise of 227,273 Class N Warrants to purchase shares of stock for $0.11 per share under the terms of the Class N warrant agreement, for cash consideration of $25,000.

Class O Warrants Issuances

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

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

On December 11, 2017, in consideration for services rendered, the Company issued Class O Warrant Agreements to active employees, independent contractors, members of the board of directors and members of the medical advisory boards to purchase 3,940,000 shares of common stock at an exercise price of $0.11 per share. Kevin A. Richardson II and A. Michael Stolarski, both members of the Company's board of directors and existing shareholders of the Company, were issued 640,000 and 200,000 warrants, respectively. John Nemelka, Alan Rubino and Maj-Britt Kaltoft, members of the Company's board of directors, were each issued 200,000 warrants. Lisa E. Sundstrom, an officer of the Company was issued 440,000 warrants.

On January 6, 2018, the Company granted Class O Warrant Agreements to a vendor to purchase 100,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $13,870 and was recorded as general and administrative expense and an increase to additional paid-in capital in June 2018 when the warrants were formally issued. The warrants vested upon issuance and expire on March 17, 2019.

On January 26, 2018, the Company granted Class O Warrant Agreements to a vendor to purchase 909,091 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $160,455 and was recorded as general and administrative expense and an increase to additional paid-in capital in June 2018 when the warrants were formally issued. The warrants vested upon issuance and expire on January 25, 2022.

On February 6, 2018, the Company granted Class O Warrant Agreements to a vendor to purchase 100,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $11,200 and was recorded as general and administrative expense and an increase to additional paid-in capital in June 2018 when the warrants were formally issued. The warrants vested upon issuance and expire on March 17, 2019.

On June 28, 2018, the Company issued Class O Warrant Agreements to a vendor to purchase 400,000 shares of common stock at an exercise price of $0.11 per share. Each Class O Warrant represents the right to purchase one share of Common Stock. The estimated fair value of the Class O Warrants at the grant date was $134,360 and was recorded as general and administrative expense and an increase to additional paid-in capital. The warrants vested upon issuance and expire on March 17, 2019.

Convertible Promissory Note Issuance

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

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

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

Consulting Agreement

In May 2017, the Company entered into a consulting agreement with another vendor for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $7,500 by the Common Stock price at the close of business on the eighth business day of each month. On March 27, 2018, the Company issued 533,450 shares for services rendered May 2017 through February 2018. On June 28, 2018, the Company issued 15,000 shares for services rendered in March 2018. Non-cash general and administrative expense of $22,500 and $60,000 was recorded in 2018 and 2017, respectively.

In November 2017, the Company entered into a three month consulting agreement with a vendor for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 26,667, 23,529 and 18,182 shares, respectively in each of the three months of the agreement. The $4,000 was recorded as a non-cash general and administrative expense for each of the three months of the agreement. In April 2018, the Company verbally entered into a month-to-month consulting agreement with the same vendor for which a portion of the fee for the services was to be paid with Common Stock. The number of shares to be paid with Common Stock was calculated by dividing the amount of the fee to be paid with Common Stock of $4,000 by the Company stock price at the close of business on the eighth business day of each month. The Company issued 26,667, 23,529 and 18,182 shares, respectively in each of the three months of the agreement. The $20,000 was recorded as a non-cash general and administrative expense upon issuance in June 2018.

On October 17, 2018, the Company and a vendor agreed to settle a portion of a previously incurred fee for services in Common Stock in lieu of cash. On October 17, 2018, the Company issued 426,176 shares for services rendered May 2017 through February 2018. Non-cash general and administrative expense of $15,000 and $60,000 was recorded in 2018 and 2017, respectively.

10% Convertible Promissory Notes Issuances

On March 27, 2017, the Company began offering subscriptions for 10% convertible promissory notes (the “10% Convertible Promissory Notes”) to selected accredited investors. The Company intends to use the proceeds from the 10% Convertible Promissory Notes for working capital and general corporate purposes. The initial offering closed on August 15, 2017, at which time $55,000 aggregate principal amount of 10% Convertible Promissory Notes were issued and the funds paid to the Company. Subsequent offerings were closed on November 3, 2017, November 30, 2017, and December 21, 2017, at which times $1,069,440, $259,310 and $150,000, respectively, aggregate principal amounts of 10% Convertible Promissory Notes were issued and the funds paid to the Company. The 10% Convertible Promissory Notes include a warrant agreement (the “Class N Warrant Agreement”) to purchase Common Stock equal to the amount obtained by dividing the (i) sum of the principal amount, by (ii) $0.11. The Class N Warrant Agreement expires March 17, 2019. On November 3, 2017, the Company issued 10,222,180 Class N Warrants in connection with the initial and second closings of 10% Convertible Promissory Notes. On November 30, 2017, and December 21, 2017, the Company issued 2,357,364 and 1,363,636, respectively, Class N Warrants in connection with the closings of 10% Convertible Promissory Notes. A. Michael Stolarski, a member of the Company’s board of directors and an existing shareholder of the Company, was a purchaser in the 10% Convertible Promissory Notes in the amount of $330,000. A. Michael Stolarski and Kevin A. Richardson II, both members of the Company’s board of directors and existing shareholders of the Company, had subscribed $130,000 and $140,000, respectively, to the Company as advances from related parties to be used to purchase 10% Convertible Promissory Notes. The 10% Convertible Promissory Notes associated with these subscriptions were issued in January 2018. Sales commissions of $72,625 were paid to WestPark Capital, Inc. in connection with these offerings.

A subsequent offering of the 10% Convertible Promissory Notes was closed on January 10, 2018, at which time $1,496,000 aggregate principal amount of 10% Convertible Promissory Notes were issued with $1,066,000 of funds paid to the Company. The remaining $430,000 of principal came from advances from related and unrelated parties balance at December 31, 2017 of $310,000 (see Note 7) and conversion of $120,000 of unpaid executive compensation by related party, Kevin A. Richardson II. On January 10, 2018, the Company issued 13,599,999 Class N Warrants in connection with such subsequent closing. Sales commission of $64,100 was paid to WestPark Capital, Inc. in connection with this offering.

On February 15, 2018, the Company defaulted on the 10% Convertible Promissory Notes issued on August 15, 2017 and began accruing interest at the default interest rate of 18%.

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

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

On July 20, 2018, the Company issued 954,545 shares of restricted common stock upon the conversion of 10% Convertible Promissory Notes in the amount of $100,000 plus accrued interest of $5,000 at the conversion price of $0.11 per share per the 10% Convertible Promissory Notes agreement.

On July 20, 2018, the Company issued 500,000 shares of common stock upon the partial conversion of 10% Convertible Promissory Notes in the amount of $55,000 at the conversion price of $0.11 per share per the 10% Convertible Promissory Notes agreement.

On August 6, 2018, the Company issued 683,042 shares of restricted common stock upon the conversion of 10% Convertible Promissory Notes in the amount of $71,500 plus accrued interest of $3,635 at the conversion price of $0.11 per share per the 10% Convertible Promissory Notes agreement.

On August 15, 2018, the Company issued 462,924 shares of free trading Common Stock upon the conversion of 10% Convertible Promissory Notes in the amount of $45,000 plus accrued interest of $50,922 at the conversion price of $0.11 per share per the 10% Convertible Promissory Notes agreement.

All such conversions of 10% Convertible Promissory Notes were exempt from registration pursuant to Section 3(a)(9).

Cashless Warrant Exercise, Exempt From Registration Pursuant to Securities Act Section 3(a)(9)

On August 23, 2016, the Company issued 343,434 shares of Common Stock to JDF Capital, Inc. upon the cashless exercise of 971,667 Class M Warrants to purchase shares of stock for $0.06 per share based on a current market value of $0.17 per share as determined under the terms of the Class M Warrant agreement.

On August 23, 2016, the Company issued 1,640,589 shares of Common Stock to JDF Capital, Inc. upon the cashless exercise of 4,641,667 Class J Warrants to purchase shares of stock for $0.06 per share based on a current market value of $0.17 per share as determined under the terms of the Class J Warrant agreement.

On September 8, 2016, the Company issued 526,288 shares of Common Stock to Vigere Capital LP upon the cashless exercise of 971,667 Class M Warrants to purchase shares of stock for $0.06 per share based on a current market value of $0.11 per share as determined under the terms of the Class M Warrant agreement.

On November 18, 2016, the Company issued 117,510 shares of Common Stock to DeMint Law, PLLC upon the cashless exercise of 143,400 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.185 per share as determined under the terms of the Series A Warrant agreement.

On January 20, 2017, the Company issued 15,951 shares of Common Stock to Intracoastal Capital, LLC upon the cashless exercise of 20,000 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.165 per share as determined under the terms of the Series A Warrant agreement.

On January 26, 2017, the Company issued 79,998 shares of Common Stock to Intracoastal Capital, LLC upon the cashless exercise of 100,000 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.1669 per share as determined under the terms of the Series A Warrant agreement.

On February 2, 2017, the Company issued 158,240 shares of Common Stock to Intracoastal Capital, LLC upon the cashless exercise of 200,000 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.17 per share as determined under the terms of the Series A Warrant agreement.

On February 6, 2017, the Company issued 80,804 shares of Common Stock to Intracoastal Capital, LLC upon the cashless exercise of 100,000 Series A Warrants to purchase shares of stock for $0.0334 per share based on a current market value of $0.174 per share as determined under the terms of the Series A Warrant agreement.

On March 13, 2017, the Company issued 297,035 shares of Common Stock to Lucas Hoppel upon the cashless exercise of 583,333 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.163 per share as determined under the terms of the Class L Warrant agreement.

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

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

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

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

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

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

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

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

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

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

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

On June 5, 2018, the Company issued 322,687 shares of common stock upon the cashless exercise of 400,000 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.3339 per share as determined under the terms of the Class L Warrant agreement.

On June 22, 2018, the Company issued 80,164 shares of common stock upon the cashless exercise of 100,000 Class L Warrants to purchase shares of stock for $0.08 per share based on a current market value of $0.4033 per share as determined under the terms of the Class L Warrant agreement.

On July 2, 2018, the Company issued 653,859 shares of common stock upon the cashless exercise of 909,091 Class N Warrants to purchase shares of stock for $0.11 per share based on a current market value of $0.3918 per share as determined under the terms of the Class N Warrant agreement.

August 2016 Private Placement

On August 24, 2016, the Company entered into a Securities Purchase Agreement with certain accredited investors (the "Purchasers") for the issuance of an aggregate total 28,300,001 shares of Common Stock for an aggregate total purchase price of $1,698,000 (the "August 2016 Private Placement"). The Company has used the proceeds from the August 2016 Private Placement for working capital and general corporate purposes. In addition, the Company, in connection with the August 2016 Private Placement, issued to the Purchasers an aggregate total of 28,300,001 Class L warrants to purchase shares of Common Stock at an exercise price of $0.08 per warrant. Each Class L warrant represents the right to purchase one share of Common Stock. The Class L warrants vested upon issuance and expire on March 17, 2019. Anthony M. Stolarski, a member of our board of directors and an existing shareholder of the Company and Michael Nemelka, the brother of a member of our board of directors and an existing shareholder of the Company, were purchasers in the August 2016 Private Placement. At the closing of the August 2016 Private Placement, the Company paid WestPark Capital, Inc., the placement agent for the August 2016 Private Placement, a fee of (i) ten percent of the aggregate purchase price of the securities sold in the August 2016 Private Placement and (ii) warrants to purchase ten percent of the number of shares sold in the August 2016 Private Placement. Accordingly, the placement agent was issued Class L warrants to purchase 2,830,000 shares of Common Stock at an exercise price of $0.08 per share. As part of the August 2016 Private Placement, the Company entered into a registration rights agreement, dated August 24, 2016, with the investors in the private placement, which agreement included a registration right for the Common Stock issued in the August 2016 Private Placement and issuable upon the exercise of the Series A warrants, until the date on which such investor may sell all of registrable securities held without restriction (including volume restrictions) pursuant to Rule 144 and without the need for current public information required by Rule 144(c)(1) or the date on which the investor has sold all of registrable securities held by such investor.

In cashless exercises pursuant to Section 3(a)(9) of the Securities Act, the Purchasers have exercised 1,783,333 Class L warrants for shares of Common Stock and subsequently sold such shares pursuant to Rule 144. In a cashless exercise pursuant to Section 3(a)(9) of the Securities Act, the Placement Agent has exercised 990,500 Class L warrants and subsequently sold the shares received upon such cashless exercise pursuant to Section 4(a)(3) of the Securities Act.

Private Placement Convertible Debenture Investment

On July 29, 2016, the Company entered into a financing transaction for the sale of a Convertible Debenture (the "Debenture") in the principal amount of $200,000, with gross proceeds of $175,000 to the Company after payment of a 10% original issue discount. The offering was conducted pursuant to the exemption from registration provided by Section 4(a)(2) of the Act and Rule 506 of Regulation D thereunder. The Company did not utilize any form of general solicitation or general advertising in connection with the offering. The Debenture was offered and sold to one accredited investor.

The Debenture was issued pursuant to the terms of a purchase agreement between the Company and the investor. The Debenture was secured by the accounts receivable of the Company and, unless earlier redeemed, matured on the third anniversary date of issuance. The Company paid to the investor a non-accountable fee (the "Commitment Fee") of (i) $2,500.00 and (ii) 835,000 shares of restricted Common Stock for the investor's expenses and analysis performed in connection with the analysis of the Company and the investor's making the contemplated investment. The Commitment Fee was paid on the signing closing date immediately upon receipt of the signing purchase price.

In September 2016, the Company repaid the Debenture in full, which totaled $210,000 with a Redemption Price of 105% of the sum of the Principal Amount per the agreement.

Consulting Agreements

On May 1, 2017, the Company entered into an agreement with an investment company to provide business advisory and consulting services. The compensation for those services was to be paid in a combination of cash and Common Stock. At December 31, 2017, the Company accrued $120,000 of expense for the services provided. The common stock was issued in March 2018 in the amount of 467,423 shares.

In August 2016, the Company entered into a consulting agreement for which the fee for the services performed was paid with Company common stock. The Company issued 435,392 shares of common stock to Vigere Capital LP under this agreement. The fair value of the common stock issued to the consultant, based upon the closing market price of the Company's common stock at the date the common stock was issued, was recorded as a non-cash general and administrative expense for the year ended December 31, 2016.

August 2016 Warrants issued for consulting services

In August 2016, the Company issued 2,140,000 warrants to purchase shares of Common Stock at an exercise price of $0.08 per warrant to Millennium Park Capital LLC as compensation for certain consulting services. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019. This issuance was made pursuant to the exemption from registration provided by Section 4(a)(2) of the Act and Rule 506 of Regulation D thereunder. The Company did not utilize any form of general solicitation or general advertising in connection with the issuance.

June 2016 Warrants issued for consulting services

In June 2016, the Company issued 500,000 warrants to purchase shares of Common Stock at an exercise price of $0.08 per warrant to Millennium Park Capital LLC as compensation for certain consulting services. Each Class L Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire on March 17, 2019. This issuance was made pursuant to the exemption from registration provided by Section 4(a)(2) of the Act and Rule 506 of Regulation D thereunder. The Company did not utilize any form of general solicitation or general advertising in connection with the issuance.

Employee Stock Option Grant

On October 1, 2015, the Company granted to the active employees, members of the board of directors and members of the medical advisory board options to purchase 1,900,000 shares of common stock at an exercise price of $0.11 per share and 1,450,000 shares of common stock at an exercise price of $0.50 per share. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.10567 resulting in compensation expense of $354,000. Compensation cost was recognized at grant date.

On June 16, 2016, the Company granted to the active employees, members of the board of directors and two members of the Company’s Medical Advisory Board options to purchase 3,300,000 shares each of the Company’s common stock at an exercise price of $0.04 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.0335 resulting in compensation expense of $110,550. Compensation cost was recognized upon grant.

On November 9, 2016, the Company granted to the active employees, members of the board of directors and two members of the Company’s Medical Advisory Board options to purchase 2,830,000 shares each of the Company’s common stock at an exercise price of $0.18 per share and vested upon issuance. Management will utilize the Black-Scholes option pricing model to determine the fair value of the options per shares and record the appropriate compensation cost as of grant.

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

On June 18, 2018, the Company granted to a new employee options to purchase 30,000 shares of the Company’s common stock at an exercise price of $0.40 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.3882 resulting in compensation expense of $11,646. Compensation cost was recognized upon grant.

On May 31, 2018, the Company granted to a new employee options to purchase 2,000,000 shares of the Company's common stock at an exercise price of $0.42 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.3879 resulting in compensation expense of $775,800. Compensation cost was recognized upon grant.

On April 1, 2018, the Company granted to a new employee options to purchase 100,000 shares of the Company's common stock at an exercise price of $0.11 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.4932 resulting in compensation expense of $49,350. Compensation cost was recognized upon grant.

On September 20, 2018, the Company granted to the active employees, members of the board of directors and members of the Company's Medical Advisory Board options to purchase 7,950,000 shares each of the Company's common stock at an exercise price of $0.21 per share and vested upon issuance. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of $0.206 resulting in compensation expense of $1,637,700. Compensation cost was recognized upon grant.

2016 Series A Warrant Exchange, Exempt From Registration Pursuant to Securities Act Section 3(a)(9)

On January 13, 2016, the Company entered into an exchange agreement (the "Exchange Agreement") with certain holders of the Series A warrants issued in the March 2014 Private Placement and in the 18% Convertible Note Conversion, pursuant to which such holders exchanged such Series A warrants for either (i) shares of Common Stock or (ii) shares of Common Stock and shares of the Company's Series B Convertible Preferred Stock. The exchange was based on the exchange ratio whereby one Series A warrant was exchanged for 0.4685 shares of Common Stock. Holders who, as a result of the exchange, would own in excess of 9.99% of the outstanding Common Stock (the "Ownership Threshold") received a mixture of Common Stock and shares of Series B Convertible Preferred Stock, namely Common Stock up to the Ownership Threshold and shares of Series B Convertible Preferred Stock beyond the Ownership Threshold (with the total shares of Common Stock and Series B Convertible Preferred Stock issued to such holders based on the same exchange ratio). The relative rights, preferences, privileges and limitations of the Series B Convertible Preferred Stock were as set forth in the Company's Certificate of Designation of Series B Convertible Preferred Stock, which was filed with the Secretary of State of the State of Nevada on January 12, 2016 (the "Series B Certificate of Designation"). In the exchange, an aggregate number of 23,701,428 Series A warrants, which represented 22,437,500 Series A warrants initially issued as part of the March 2014 Private Placement and 1,263,928 Series A warrants initially issued as part of the 18% Convertible Note Conversion, were exchanged for 7,447,954 shares of Common Stock and 293 shares of Series B Convertible Preferred Stock (the "Series A Warrant Conversion"). Pursuant to the Series B Certificate of Designation, each share of Series B Convertible Preferred Stock was convertible into shares of Common Stock at an initial rate of one share of Series B Convertible Preferred Stock for 12,500 shares of Common Stock, which conversion rate was subject to further adjustment as set forth in the Series B Certificate of Designation. All 293 shares of Series B Convertible Preferred Stock were converted to 3,657,278 shares of Common Stock on April 29, 2016 (the "Preferred Stock Conversion"). In connection with entering into the Exchange Agreement, the Company also entered into a registration rights agreement, dated January 13, 2016, with the holders of the Series A warrants who participated in the exchange, which agreement included a registration right for the Common Stock issued as part of the exchange or issuable upon the conversion of the Series B Convertible Preferred Stock, until the date on which such investor may sell all of registrable securities held without restriction (including volume restrictions) pursuant to Rule 144 and without the need for current public information required by Rule 144(c)(1) or the date on which the investor has sold all of registrable securities held by such investor.

HealthTronics Warrants

On June 15, 2015, the Company, and its wholly owned subsidiary SANUWAVE, Inc., a Delaware corporation (the "Borrower") entered into an amendment (the "Amendment") to amend certain provisions of two promissory notes (the "Promissory Notes") dated August 1, 2005 between the Borrower and HealthTronics, Inc., with an aggregate outstanding principal balance of $5,372,742. In connection with the Amendment, the Company issued to HealthTronics, on June 15, 2015, an aggregate total of 3,310,000 warrants (the "Class K Warrants") to purchase shares of the Company's Common Stock, at an exercise price of $0.55 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after ten years.

On June 28, 2016, the Company and HealthTronics, Inc. entered into a second amendment (the "Second Amendment") to amend certain provisions of the notes payable, related parties. The Second Amendment provides for the extension of the due date to January 31, 2018. In addition, the Company, in connection with the Second Amendment, issued to HealthTronics, Inc. on June 28, 2016 an additional 1,890,000 Class K Warrants to purchase shares of the Company's Common Stock at an exercise price of $0.08 per share, subject to certain anti-dilution protection. The exercise price of the 3,310,000 Class K Warrants issued on June 15, 2015 was decreased to $0.08 per share.

On August 3, 2017, the Company and HealthTronics, Inc. entered into a third amendment (the “Third Amendment”) to amend certain provisions of the notes payable, related parties. The Third Amendment provides for the extension of the due date to December 31, 2018, revision of the mandatory prepayment provisions and the future issuance of additional warrants to HealthTronics upon certain conditions. In addition, the Company, in connection with the Third Amendment, issued to HealthTronics, Inc. on August 3, 2017 an additional 2,000,000 Class K Warrants to purchase shares of the Company’s Common Stock at an exercise price of $0.11 per share, subject to certain anti-dilution protection. Each Class K Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after ten years.

ITEM 16. Exhibits and Financial Statement Schedules

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).
3.4	Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
3.6	Certificate of Amendment to the Articles of Incorporation, dated September 8, 2015 (Incorporated by reference to the Form 10-K filed with the SEC on March 30, 2016).
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock of the Company dated January 12, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
4.1	Form of Class A Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.2	Form of Class B Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.3	Form of Class D Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on October 14, 2010).
4.4	Form of Class E Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).
4.5	Form of Series A Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.6	Form of 18% Senior Secured Convertible Promissory Note issued by the Company to select accredited investors (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).
4.7	Form of Convertible Promissory Note between the Company and accredited investors party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.8	Amendment No. 1 to the Convertible Note Agreement between the Company and accredited investors party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.9	Class K Warrant Agreement by and between the Company and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015).
4.10	Amendment No. 1 to Class K Warrant Agreement by and between the Company and HealthTronics, Inc., dated June 28, 2016 (Incorporated by reference to the Form 10-Q filed with the SEC on August 15, 2016).
4.11	Form of Class L Warrant Common Stock Purchase Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 17, 2016).

4.12	Second Form of Class L Warrant Common Stock Purchase Warrant (Incorporated by reference to the Form 8-K filed with the SEC on August 24, 2016).
4.13	Registration Rights Agreement dated January 13, 2016 among the Company and the investors listed therein (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
4.14	Class K Warrant Agreement dated as of August 3, 2017, between the Company and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
4.15	Form of Class N Warrant. (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
5.1*	Opinion of Hutchison &Steffen, LLC.
10.1	Amended and Restated 2006 Stock Option Incentive Plan of SANUWAVE Health, Inc. (Incorporated by reference to Form 8-K filed with the SEC on November 3, 2010).
10.2	Form of Securities Purchase Agreement, by and among the Company and the accredited investors party thereto, dated March 17, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
10.3	Form of Registration Rights Agreement, by and among the Company and the holders party thereto, dated March 17, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
10.4	Form of Subscription Agreement for the 18% Convertible Promissory Notes between the
10.5	Amendment to certain Promissory Notes that were dated August 1, 2005, by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015.)
10.6	Security Agreement, by and between the Company and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015).
10.7	Exchange Agreement dated January 13, 2016 among the Company and the investors listed therein (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
10.8	Escrow Deposit Agreement dated January 25, 2016 among the Company, Newport Coast Securities, Inc. and Signature Bank (Incorporated by reference to the Form S-1/A filed with the SEC on February 3, 2016).
10.9	Second Amendment to Certain Promissory Notes entered into as of June 28, 2016 by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to the Form 10-Q filed with the SEC on August 15, 2016).
10.10	Form of Securities Purchase Agreement, by and among the Company and the accredited investors a party thereto, dated March 11, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on March 17, 2016).
10.11	Form of Securities Purchase Agreement, by and between the Company and the accredited investors a party thereto, dated August 24, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on J August 25, 2016).
10.12	Form of Registration Rights Agreement, by and between the Company and the holders a party thereto, dated August 24, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on August 25, 2016).
10.13	Third Amendment to promissory notes entered into as of August 3, 2017 by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
10.14#	Binding Term Sheet for Joint Venture Agreement between the Company and MundiMed Distribuidora Hospitalar LTDA effective as of September 25, 2017 (Incorporated by reference to Form 10-Q filed with the SEC on November 15, 2017).
10.15	Master Equipment Lease, dated January 26, 2018, by and among the Company and NFS Leasing, Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on February 16, 2018).
10.17#	Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs of dermaPACE Systems and Equipment among the Company, and Premier Shockwave Wound Care, Inc. and Premier Shockwave, Inc. dated as of February 13, 2018 (Incorporated by reference to Form 10-K filed with the SEC on March 29, 2018).
10.18	

	Offer Letter, dated April 11, 2018, between the Company and Shri Parikh (Incorporated by reference to Form 8-K filed with the SEC on June 7, 2018).
10.19	Agreement, dated June 14, 2018, by and among the Company and Johnfk Medical Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on June 29, 2018).
10.20	Offer Letter, dated as of April 15, 2018, by and between SANUWAVE Health, Inc. and SHRI Parikh (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on June 7, 2018).
10.21	Agreement, dated June 14, 2018, by and among the Company and Johnfk Medical Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on June 29, 2018).
10.22	Joint Venture Agreement, dated September 21, 2018, by and among SANUWAVE Health, Inc., Johnfk Medical Inc. and Holistic Wellness Alliance Pte. Ltd. (formerly known as Holistic Health Institute Pte. Ltd.) (Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on September 27, 2018).
10.23	Offer Letter, dated as of November 30, 2018 by and between SANUWAVE Health, Inc. and Kevin Richardson (Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on December 4, 2018).
21.1	List of subsidiaries (Incorporated by reference to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017).
23.1*	Consent of Cherry Bekaert LLP, independent registered public accountants.
23.2*	Consent of Hutchison &Steffen, LLC (included in its opinion filed as Exhibit 5.1).
24.1**	Power of Attorney (set forth on the signature page of the registration statement).

Indicates management contract or compensatory plan or arrangement.

* Filed herewith

** Previously filed as the same-numbered exhibit to our registration statement on Form S-1 (File No. 333-213774) filed on July 2, 2018.

Confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and
submitted separately to the Securities and Exchange Commission.

ITEM 17. Undertakings

(a) The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the Registration Statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Suwanee, State of Georgia, on December 6, 2018.

SANUWAVE Health, Inc.

By: /s/ Kevin A. Richardson, II
Name: Kevin A. Richardson, II
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signatures	Capacity	Date
By: /s/ Kevin A. Richardson, II Name: Kevin A. Richardson, II	Director and Chief Executive Officer (principal executive officer)	December 6, 2018
By: /s/ Lisa Sundstrom Name: Lisa Sundstrom	Chief Financial Officer (principal financial and accounting officer)	December 6, 2018
By: * Name: John F. Nemelka	Director	December 6, 2018
By: * Name: Alan L. Rubino	Director	December 6, 2018
By: * Name: A. Michael Stolarski	Director	December 6, 2018
By: * Name: Maj-Britt Kaltoft	Director	December 6, 2018

*By: /s/ Kevin A. Richardson, II
Attorney-in-fact