SANUWAVE Health, Inc.
Form S-1/A
February 03, 2016
As filed with the Securities and Exchange Commission on February 3, 2016

Registration No. 333-208676

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITES ACT OF 1933

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

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

11475 Great Oaks Way, Suite 150

Alpharetta, Georgia 30022

(770) 419-7525

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Kevin A. Richardson, II

Acting Chief Executive Officer
SANUWAVE Health, Inc.

11475 Great Oaks Way, Suite 150
Alpharetta, Georgia 30022
(770) 419-7525

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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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, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered [1]	Amount to be registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Units [2][3]		$ -	$ 4,000,000	$ 402.80
Common Stock, $0.001 par value, included as part of the Units [4]		$ -	$ -	$ -
Warrants, included as part of the Units [4]		$ -	$ -	$ -
Common Stock Underlying Warrants [3][5]		$ -	$ -	$ -
Common Stock, $0.001 par value [6]	19,887,836	$ 0.08	$ 1,591,027	$ 160.22
Placement Agent's Warrants to acquire common stock		$ -	$ -	$ -
Common Stock issuable upon execise of the Placement Agent's Warrants		$ -	$ 400,000	$ 40.28
Total [7]	19,887,836			$ 603.30

[1] Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

[2] Each “Unit” consists of one (1) share of common stock, $0.001 par value and one (1) detachable warrant.

[3] Calculated pursuant to Rule 457(o) under the Securities Act on the basis of the maximum aggregate offering price of the securities being registered.

[4] No Registration Fee required pursuant to Rule 457(g).

[5] Calculated in accordance with Rule 457(g).

[6] Common Stock being registered for re-sale by selling shareholders. 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 January 20, 2016.

[7] The Registrant previously paid a registration fee of $492.42, and the registration fee due in connection with this filing is further offset by an additional $920.43 of unused registration fees carried forward.

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 Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. Neither the Company, nor our 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 we are not soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus, Subject to Completion, Dated February 3, 2016.

Up to $4,000,000

of

Units

(Common Stock, $0.001 par value and Warrants)

$889,993

of

Common Stock

Offered by Selling Stockholders

We are offering a minimum of 31,250,000 Units (the "*Units*"), with each Unit consisting of (i) one (1) share of our common stock, $0.001 par value (the "*Common Stock*") and, (ii) one (1) detachable warrant (the "*Warrants*") to purchase one (1) share of our Common Stock at an exercise price of $0.08 per share for gross proceeds of $2,500,000 (the "*Minimum Offering*") before deduction of commissions and offering expenses and a maximum of 50,000,000 Units for gross proceeds of $4,000,000 (the "*Maximum Offering*") before deduction of commissions and offering expenses. The Units will separate immediately and the Common Stock and Warrants will be issued separately. This offering expires on the earlier of (i) the date upon which all of the Units being offered have been sold, or (ii) February 19, 2016. In addition, we may terminate this offering at any time prior to the expiration date. All costs associated with the registration will be borne by us.

All funds sent to the Company to purchase the Units will be deposited in a non-interest bearing escrow account, maintained by Signature Bank (the "*Escrow Agent*"). Within three business days of receipt of the Minimum Offering amount in escrow the Company will first close on the subscription amounts in escrow as of such date subject to the

Maximum Offering amount, and additional closings may be held until the expiration or termination of the offering. If we do not sell and receive payments for the Minimum Offering amount prior to February 19, 2016, investor subscriptions will be returned without interest or deduction.

In addition, this prospectus relates to the sale of up to 19,887,836 outstanding shares of our Common Stock by the selling stockholders listed in this prospectus. The shares offered by this prospectus may be sold by the selling stockholders, from time to time, in the over-the-counter market or 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, or otherwise in compliance with the "Plan of Distribution" contained herein.

We will receive none of the proceeds from the sale of any shares by the selling stockholders. 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.

We have engaged Newport Coast Securities, Inc. to act as our exclusive placement agent in connection with this offering. We have agreed to pay the placement agent a cash fee of (i) ten percent (10%) of the aggregate purchase price of the Units sold in this offering and (ii) warrants to purchase ten percent (10%) of the number of shares sold in this offering. In the case of the Minimum Offering, 31,250,000 Units, the placement agent will be issued warrants to purchase 3,125,000 shares of Common Stock at an exercise price of $0.08 per share and in the case of the Maximum Offering, 50,000,000 Units, the placement agent will be issued warrants to purchase 5,000,000 shares of Common Stock at an exercise price of $0.08 per share. The registration statement of which this prospectus is a part also covers the placement agent's warrants and the shares of Common Stock issuable from time to time upon the exercise of the placement agent's warrants. The placement agent's warrants and the underlying shares of Common Stock are subject to compliance with the requirements of the Financial Industry Regulatory Authority, Inc., or FINRA.

See "Plan of Distribution" beginning on page 26 of this prospectus for more information regarding the above compensation payable to the placement agent.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol SNWV.OB. The high and low bid prices for shares of our Common Stock on January 20, 2016, were $0.09 and $0.07 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 6 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.

Brokers or dealers effecting transactions in these securities should confirm that the securities are registered under the applicable state law or that an exemption from registration is available.

Placement Agent

Newport Coast Securities, Inc.

The date of this prospectus is _____, 2016

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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.

About This Prospectus

You may rely only on the information contained in this prospectus or that we have referred you to. 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. 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 or that the information contained by reference to this prospectus is correct as of any time after its date.

Our Company

We are a shockwave technology company using a patented system of noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves 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 demaPACE® device, used for treating diabetic foot ulcers, which is in a supplemental Phase III clinical study with possible FDA approval in 2016, subject to submission of satisfactory clinical study results.

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. We currently do not market any commercial

products for sale in the United States. We generate our revenues from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

In addition, we believe that there are license/partnership opportunities for the Company's shockwave technology for non-medical uses, including energy, water, food and industrial markets. For more information about the Company, see the section entitled "Business" in this prospectus.

Product Overview; Strategy

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 and 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.

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.

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

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 clinical trials and have not yet 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 Over the Counter Bulletin Board under the symbol “SNWV.OB.”

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 11475 Great Oaks Way, Suite 150, Alpharetta, Georgia 30022, 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.

About this Offering

Securities being offered by the Company

Securities being offered by us	In the case of the Minimum Offering, 31,250,000 Units, each Unit consisting of one (1) share of Common Stock and one (1) Warrant to purchase one (1) share of Common Stock at an exercise price of $0.08 per share. In the case of the Maximum Offering, 50,000,000 Units.
Offering price	$0.08 per Unit.
Description of Warrants	The warrants will be exercisable at any time during the period commencing on the date of closing of the offering and ending on March 17, 2019 at an exercise price per share equal to $0.08.
Shares of Common Stock that may be issued upon the exercise of Warrants issued as part of the Units	In the case of the Minimum Offering, 31,250,000 shares of Common Stock. In the case of the Maximum Offering, 50,000,000 shares of Common Stock.
Use of proceeds	We intend to use the net proceeds from the sale of Units by us primarily for expenses related to the Premarket Approval (PMA) submission to the FDA of dermaPACE for treating diabetic foot ulcers in the United States, commercialization of dermaPACE in the United States and for other general corporate purposes.
Expiration time/date	February 19, 2016
Shares of Common Stock outstanding before this offering	70,504,473 shares[(1)]
Shares of Common Stock to be outstanding after this offering	In the case of the Minimum Offering, 94,306,519 (125,556,519 shares if the Warrants are exercised in full) of Common Stock. In the case of the Maximum Offering, 113,056,519 (163,056,519 shares if the Warrants are exercised in full) of Common Stock.
Escrow	All funds sent to the Company to purchase the Units will be deposited in a non-interest bearing escrow account, maintained by Signature Bank (the “Escrow Agent”) at a bank account at the branch of Signature bank selected by the Escrow Agent. Within three business days of receipt of the Minimum Offering amount in escrow the Company will first close on the subscription amounts in escrow as of such date subject to the Maximum Offering amount, and additional closings may be held until the expiration or termination of the offering. If we do not

	sell and receive payments for the Minimum Offering amount prior to February 19, 2016, investor subscriptions will be returned without interest or deduction.
Subscription Procedures	Investors interested in subscribing for the Units in this offering must complete and deliver to the Placement Agent a completed subscription agreement to the address provided in the subscription agreement and deliver the purchase price by wire transfer in immediately available funds using the wire transfer instructions provided in the subscription agreement. Funds and subscription documents will be held in escrow until the first closing of this offering at which time the escrowed funds and subscription documents will be released by the Escrow Agent. Promptly following the first closing the Units purchased by the investor in the offering will be issued to the investor. If this offering is not completed for any reason all proceeds deposited into escrow will be returned to the investor without interest or deduction.
OTC Bulletin Board market symbol	SNWV
Risk factors	See “Risk Factors” beginning on page 5 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Common Stock.

Securities being offered by the Selling Stockholders

Common Stock	19,887,836 shares.
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares by the selling stockholders.
Risk Factors	See "Risk Factors" beginning on page 6 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Common Stock.

(1) The number of shares shown to be outstanding is based on the number of shares of our Common Stock outstanding as of January 20, 2016, and does not include shares reserved for issuance upon the exercise of warrants outstanding, or options granted or available under our equity compensation plans.

SUMMARY FINANCIAL INFORMATION

The summary financial information set forth below is derived from and should be read in conjunction with our consolidated financial statements, including the notes thereto, appearing at the end of this prospectus.

	Nine Months Ended		Year Ended	
	September 30, 2015	September 30, 2014	December 31, 2014	December 31, 2013
Consolidated Statement of Operations Data				
Revenue	$594,040	$610,705	$847,367	$800,029
Net loss	$(3,707,492)	$(5,750,509)	$(5,974,080)	$(11,299,721)
Weighted average shares outstanding	63,014,763	46,258,912	48,212,910	28,132,134
Net loss per share - basic and diluted	$(0.06)	$(0.12)	$(0.12)	$(0.40)
Consolidated Balance Sheet Data (at end of period)				
Working capital deficit	$(183,596)	$(1,131,755)	$(2,183,859)	$(1,700,118)
Total assets	$1,500,743	$5,912,688	$4,666,355	$1,588,057
Total liabilities	$6,627,081	$6,334,199	$6,217,755	$7,715,938
Total stockholders' deficit	$(5,126,338)	$(421,511)	$(1,551,400)	$(6,127,881)

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

We generate only minimal revenues and we continue to experience operating losses.

Since our inception, we have experienced recurring losses from operations. As of September 30, 2015, we had an accumulated deficit of $91,891,615. We generate only minimal revenues and we continue to experience operating losses. We anticipate that our operating losses will continue and we will continue to incur losses in future periods unless and until we are successful in significantly increasing our revenues and cash flow. There are no assurances that we will be able to increase our revenues and cash flow to a level which supports profitable operations and provides sufficient funds to pay our obligations.

We will be required to raise additional funds to finance the commercialization of the dermaPACE, assuming FDA approval in 2016; 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. At September 30, 2015, we had cash and cash equivalents totaling $625,450. For the nine months ended September 30, 2015 and 2014, the net cash used by operating activities was $3,007,790 and $5,542,192, respectively. For the years ended December 31, 2014 and 2013, our net cash used by operating activities was $6,678,369 and $3,924,204, respectively. We need additional financial support for the commercialization of the dermaPACE, assuming FDA approval in 2016, which may include: raising additional capital through the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, an investment by a strategic partner in a specific clinical indication or market opportunity; or selling all or a portion of our assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. We will require additional capital to support development and continue our operations. Such additional capital may not be available on terms that are favorable to us, if at all. If we are unable to raise such additional funds, we may be forced to cease operations.

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, 2015, we had a net loss of $3,707,492 and used $3,007,790 of cash in operations. For the year ended December 31, 2014, we had a net loss of $5,974,080 and used $6,678,369 of cash in operations. For the year ended December 31, 2013, we had a net loss of $11,299,721 and used $3,924,204 of cash in operations. As of September 30, 2015, we had an accumulated deficit of $91,891,615 and a total stockholders' deficit of $5,126,338. 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 seeking FDA approval for our dermaPACE device. Even if we succeed in developing and commercializing one or more of our 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 future clinical trials and product development could be limited and our long term 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. 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.

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:

- unforeseen developments during our clinical trials;
- delays in timing of receipt of required regulatory approvals;
- 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;
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;
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 or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

We are no longer able to rely on Prides Capital Partners, LLC and NightWatch Capital LLC for financial support, and as a result must rely on third parties for financing.

In the past, we have relied on Prides Capital Partners, LLC (together with its affiliates, "*Prides Capital*") and NightWatch Capital LLC (together with its affiliates, "*NightWatch Capital*") for the ongoing financial support necessary to operate our business. At the time of this prospectus, both Prides Capital and NightWatch Capital have liquidated or are in the process of doing so, and they will not provide us with any additional financing or financial support in the future. To the extent we must obtain financing to support our cash needs, we will be entirely reliant on unrelated third parties. We do not have any lines of credit or other financing arrangements in place with banks or other financial institutions. We will require additional financing in the future, and additional financing may not be available at times, in amounts or on terms acceptable to us, or at all, which would have a material adverse effect on our business.

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 the 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;
- 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. 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 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.

We currently purchase most of our product component materials from single suppliers. 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. 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. 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.

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

As a small company with seven employees, our success depends on the continuing contributions of our management team and qualified personnel. 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.

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 candidate may not prove to be safe or effective;
- the product candidate's 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, 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, our products and product candidates, and 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 to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA will not indentify compliance issues that may disrupt production or distribution, or require substantial resources to correct.

The FDA's requirements may change and additional government 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 dermaPACE clinical trial, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.

We have engaged a clinical research organization (CRO) and other third party vendors to assist in the conduct of our clinical trial for dermaPACE. 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 dermaPACE clinical trial, the commercial prospects for the product could be harmed and our ability to generate product revenue would be delayed or prevented. Any failure of our CRO and other third party vendors to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides 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 our 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 trial, 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 trial 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 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.

Healthcare policy changes may have a material adverse effect on us.

In March 2010, President Obama 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, beginning in 2013;
- 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.

Certain of these provisions are still being implemented, and could meaningfully change the way healthcare is delivered and financed, and could have a material adverse impact on numerous aspects of our business. In the future 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 markets where we do business. We could experience an adverse impact on our operating results due to increased pricing pressure in the United States and in other 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 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.

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 and similar state laws. We believe our operations are in compliance with the Federal Anti-Kickback Statute 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 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.

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 will conduct experiments that are common in the medical device industry, 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 or license, 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 the 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 the 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 which 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 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 offices 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 have been or may be owned by 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 or licensed to us or that may in the future be owned by us or 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 or against us may result in determinations that patents that have been issued 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. 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 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 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 Bulletin Board (OTCBB), which is an inter-dealer, over-the-counter 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 OTCBB 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 SEC's 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 (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 our Common Stock may be impaired by the potential rights of future holders (if any) of the Companys' 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.

Although we have no present intention to issue any additional 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, 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.

If the Company only raises the Minimum Offering Amount, we may not have sufficient capital to execute our business strategy.

If we close on the Minimum Offering, we may not have sufficient capital to execute on our business strategy the way we have intended. Our ability to obtain additional financing thereafter may have a materially adverse effect on our ability to execute its overall plan and your investment may be lost.

Investor funds will not accrue interest while in escrow prior to closing.

All funds delivered by investors in the United States in connection with subscriptions for the Common Stock and Warrants will be held in a non-interest bearing escrow account with the Escrow Agent until the closing of the offering, if any. If we are unable to sell and receive payments for the Minimum Offering Amount prior to February 19, 2016, investor subscriptions will be returned without interest or deduction. Investors in the Units offered hereby may not have the use of such funds or receive interest thereon pending the completion of the offering.

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;
- timing of clinical studies and eventual FDA approval of our products;
- our marketing and manufacturing capacity and strategy;
- estimates regarding our capital requirements, and anticipated timing of the need for additional funds;
- product liability claims;
- economic conditions that could adversely affect the level of demand for 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 SEC after the date of this prospectus.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of Units by us, assuming the sale of all of the Units will be approximately $3,580,000 in the case of the Maximum Offering, and $2,230,000 in the case of the Minimum Offering, after deducting estimated offering expenses payable by us, based upon an assumed public offering price of $0.08 per Unit.

We intend to use the net proceeds from the sale of Units by us primarily for expenses related to the PMA submission to the FDA of dermaPACE for treating diabetic foot ulcers in the United States, commercialization of dermaPACE in the United States and for other general corporate purposes.

Until we use the net proceeds of this offering, we may invest the net proceeds in short-term, investment-grade securities. We cannot predict whether the proceeds invested will yield a favorable return.

This prospectus also relates to shares of our Common Stock that may be offered and sold from time to time by the selling stockholders who will receive all of the proceeds from the sale of the shares. We will not receive any proceeds

from the sale of shares of Common Stock by selling stockholders in this offering.

We will bear all expenses of registration incurred in connection with this offering, but all commissions, selling and other expenses incurred by the selling stockholders to underwriters, agents, brokers and dealers will be borne by them. We estimate that our expenses in connection with the filing of the registration statement of which this prospectus is a part will be approximately $45,000.

SELLING STOCKHOLDERS

This prospectus relates to the possible resale of up to 19,887,836 shares of our Common Stock that were issued and outstanding as of the date of the effectiveness of the registration statement of which this prospectus forms a part.

Selling Stockholder Table

The table set forth below lists the selling stockholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder) of the shares of Common Stock held by each of the selling stockholders.

The selling stockholders identified in this prospectus may offer the shares of our common stock at prevailing market prices at the time of sale, at prices related to the prevailing market price, 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 of the shares of common stock upon any exchange.

	Number of Shares beneficially owned prior to this offering (1)		**Number of Shares being offered**		**Number of Shares beneficially owned after this offering (11)**	
Name of Beneficial Owner	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Directors and Executive Officers:						
Kevin A. Richardson, II (2)	8,902,588	12.6%	406,244	0.6%	8,496,344	7.5%
John F. Nemelka (3)	382,248	0.6%	46	*	382,202	0.3%
Alan Rubino (4)	350,000	0.5%	-	-		
All directors and executive officers as a group (3 persons)	9,634,836	13.7%	-	-		
Principal and/or Selling Shareholders:						
RA Capital Healthcare Fund, L.P. (5)	6,299,346	8.9%	6,299,346	8.9%	-	-
Prides Capital Fund I, LP (6)	5,514,081	7.8%	4,851,719	6.9%	5,514,081	4.9%
Tudor BVI Global Portfolio Ltd. (7)	1,494,552	2.1%	1,494,552	2.1%	-	-
A. Michael Stolarski (8) (9)	1,233,444	1.7%	1,233,444	1.7%	-	-
NightWatch Capital Partners, LP (10)	1,020,446	1.4%	1,020,446	1.4%	-	-

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The Trustees of Columbia University in City of New York [7]	656,074	0.9%	656,074	0.9%	-	-
NightWatch Capital Partners (Cayman) Ltd. [10]	454,101	0.6%	454,101	0.6%	-	-
Crown Investment Fund [7]	238,585	0.3%	238,585	0.3%	-	-
MAZ Partners LP [9]	201,085	0.3%	201,085	0.3%	-	-
AMA U.S. Equity Opportunity Fund (QP) LP [10]	182,296	0.3%	182,296	0.3%	-	-
Brenda Hall [8]	163,991	0.2%	163,991	0.2%	-	-
Hallador Alternative Assets Fund,LLC [7]	158,649	0.2%	158,649	0.2%	-	-
Palladian Partners IV, LLC [7]	152,244	0.2%	152,244	0.2%	-	-
Oppenheimer & Co., Inc. [8]	149,349	0.2%	149,349	0.2%	-	-
HealthTronics, Inc. [7]	138,782	0.2%	138,782	0.2%	-	-
Michael S. Barish [8]	129,867	0.2%	129,867	0.2%	-	-
Frederick Wahl [8]	117,137	0.2%	117,137	0.2%	-	-
John S. Irish [8]	117,137	0.2%	117,137	0.2%	-	-
Dassity, Inc. [8]	106,209	0.2%	106,209	0.2%	-	-
Palladian Partners V, LLC [7]	88,756	0.1%	88,756	0.1%	-	-
Fred Bohlander [8]	88,618	0.1%	88,618	0.1%	-	-
Sharon Borg Wall [8]	88,286	0.1%	88,286	0.1%	-	-
Echelon Partners LP [7]	82,055	0.1%	82,055	0.1%	-	-
El Coronado Holdings, LLC [7]	71,517	0.1%	71,517	0.1%	-	-
Thunder Basin Corporation [10]	65,800	0.1%	65,800	0.1%	-	-
Taylor Waypoint Fund, LP [10]	61,359	0.1%	61,359	0.1%	-	-
Nortrust Nominees Ltd Leperq Amcur Sicav FIS [7]	61,020	0.1%	61,020	0.1%	-	-
John M. Fay [8]	59,666	0.1%	59,666	0.1%	-	-
Palladian Partners V-A, LLC [7]	59,170	0.1%	59,170	0.1%	-	-
Hallador Balance Fund LLC [7]	58,019	0.1%	58,019	0.1%	-	-
Lime Partners, LLC [7]	49,380	0.1%	49,380	0.1%	-	-
Belfer Investment Partners, LP [7]	49,380	0.1%	49,380	0.1%	-	-
Robert A. Belfer Descendants' Trust [7]	49,380	0.1%	49,380	0.1%	-	-
Stacy Family Trust [10]	47,710	0.1%	47,710	0.1%	-	-
Nortrust Nominees A/C Leperq-Lynx Partner [7]	44,700	0.1%	44,700	0.1%	-	-
The Indick/Lachman Revocable Trust [7]	44,262	0.1%	44,262	0.1%	-	-
Nightwatch Capital Management, LLC [7]	40,025	0.1%	40,025	0.1%	-	-
Lynx Managed Equity Master Fund, LP [7]	36,833	0.1%	36,833	0.1%	-	-
P. Paul and Assocaites [7]	31,495	*	31,495	*	-	-
Taylor Insurance Series LP - Series G [7]	30,916	*	30,916	*	-	-
Carlson Capital, LP [7]	29,712	*	29,712	*	-	-
Charlie McCarthy [7]	27,081	*	27,081	*	-	-
Booth and Company, Nominee A/C Lepercq Partners Fund, L.P. [7]	25,984	*	25,984	*	-	-
Peter T. Paul Living Trust [7]	25,792	*	25,792	*	-	-
KMS Opportunity Fund [7]	25,212	*	25,212	*	-	-
Renee Holdings Partnership, LP [7]	24,689	*	24,689	*	-	-
2006 Paul Partnership, LP [7]	24,445	*	24,445	*	-	-
Elizabeth Rice Grossman Family Trust [7]	23,839	*	23,839	*	-	-
Elizabeth Grossman IRA [7]	23,802	*	23,802	*	-	-
Hank Lawlor [7]	16,658	*	16,658	*	-	-
Nadel & Gussman Combined Funds, LLC [10]	16,141	*	16,141	*	-	-
Berkowitz Trust U/A/D 9/01/95 [7]	15,470	*	15,470	*	-	-
Taylor Investments Class F [7]	14,924	*	14,924	*	-	-

Christian Puscasiu [7]	12,108	*	12,108	*	-	-
Murray Indick, IRA / RO [7]	11,306	*	11,306	*	-	-
Michael Weinberg [7]	9,760	*	9,760	*	-	-

George Johnson [8]	7,450	*	7,450	*	-	-
Nicholas A Halaby [7]	5,954	*	5,954	*	-	-
Rob Santangelo, IRA [7]	5,954	*	5,954	*	-	-
Jeff and Janice Mondry [7]	5,554	*	5,554	*	-	-
Stephen E. Cootey [7]	5,244	*	5,244	*	-	-
Lawrence Becerra [10]	5,014	*	5,014	*	-	-
KCS [7]	4,986	*	4,986	*	-	-
Roy Trice [7]	4,814	*	4,814	*	-	-
Demar-Collins Children's Trust [10]	4,712	*	4,712	*	-	-
Robert J. Leerink [7]	4,061	*	4,061	*	-	-
Intellivestor, LLC [7]	3,519	*	3,519	*	-	-
Christian Puscasiu Roth [7]	3,096	*	3,096	*	-	-
Charlie McCarthy, IRA [7]	3,011	*	3,011	*	-	-
Paul Harris [10]	2,761	*	2,761	*	-	-
Stuart Harris [10]	2,761	*	2,761	*	-	-
Brad and Kelly Eichler [7]	2,391	*	2,391	*	-	-
Charles Jobson [7]	2,382	*	2,382	*	-	-
Michael McCarthy [7]	2,368	*	2,368	*	-	-
Peter Zecca, Jr. [7]	2,353	*	2,353	*	-	-
Christopher Wynne [8]	1,335	*	1,335	*	-	-
Ameriprise Financial, FBO Paul V. Burgon IRA [10]	744	*	744	*	-	-
Youghiogheny Holdings [7]	518	*	518	*	-	-
Paul Burgon [10]	229	*	229	*	-	-
Asagard investment Corporation [7]	52	*	52	*	-	-

(1) Applicable percentage ownership is based on 70,504,473 shares of common stock outstanding as of January 15, 2016, “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 January 15, 2016. 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) Includes options to purchase up to 865,000 shares of common stock and warrants to purchase up to 218,947 shares of common stock. In addition, this amount includes 5,805,371 shares of common stock and warrants to purchase 662,362 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.

(3) Includes options to purchase up to 365,000 shares of common stock. In addition, this amount includes warrants to purchase 16,702 shares of common stock owned directly by NightWatch Capital Partners II, L.P. NightWatch Capital

Management, LLC, is the general partner of NightWatch Capital Partners II, L.P. and Mr. John Nemelka is the controlling shareholder of NightWatch Capital Management LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. John Nemelka has also been deputized by NightWatch Capital Management LLC to serve on the board of directors of the Company. Mr. John Nemelka 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.

(4) Consists of options to purchase up to 350,000 shares of common stock.

(5) Shares reported herein for RA Capital Healthcare Fund, L.P. represent 5,291,451 shares of common stock issued upon the conversion of Series A Warrants held of record by the fund. Shares reported herein for RA Capital Management, LLC represent (a) the above-referenced shares of common stock issuable upon the conversion of certain warrants as reported for RA Capital Healthcare Fund, L.P. for which RA Capital Management, LLC serves as the sole general partner, and (b) 1,007,895 shares of shares of common stock issued upon the conversion of Series A Warrants held in a separately managed account for Blackwell Partners, LLC for which RA Capital Management, LLC serves as investment adviser. Each of the Reporting Persons disclaims beneficial ownership of the shares reported herein except to the extent of its or his pecuniary interest therein. The principal business office of the Reporting Persons is c/o RA Capital Management, LLC, 20 Park Plaza, Suite 1200, Boston, MA 02116.

(6) Based solely on information contained in filings on Schedule 13D, as amended, made with the SEC by the reporting person and on records of the Company. Includes warrants to purchase 662,362 shares of common stock. The principal business address of Prides Capital Fund, I, LP is 100 Cummings Center, Suite 324C, Beverly, MA 01915. Kevin A. Richardson, II, has voting and dispositive power over the securities. See footnote (2).

(7) Based on the distribution of shares of Prides Captial Fund I, L.P. in September 2015.

(8) Shares issued in conversion of Series A Warrants into Common Stock on January 14, 2016.

(9) Based on records of the Company.

(10) Based on the distribution of shares of NightWatch Capital Partners II, L.P.

(11) Assumes the sale of all of the shares offered by the selling stockholders under this prospectus and 120,504,473 shares of Common Stock outstanding after this offering, giving pro forma effect to the case of the Maximum Offering.

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PLAN OF DISTRIBUTION

Distribution

Newport Coast Securities, Inc. which we refer to herein as the Placement Agent, has agreed to act as a placement agent in connection with this offering subject to the terms and conditions of the placement agent agreement dated December 11, 2015. The Placement Agent is not purchasing or selling any securities offered by this prospectus, nor is it required to arrange the purchase or sale of any specific number or dollar amount of securities, but has agreed to use their best efforts to arrange for the sale of all or none of at least the Minimum Offering of Units offered hereby. Therefore, we will enter into a subscription agreement directly with investors in connection with this offering and we may not sell the entire amount of securities offered pursuant to this prospectus. The Placement Agent may retain other brokers or dealers to act as sub-agents or selected-dealers on its behalf in connection with the offering.

We have agreed to pay the Placement Agent a fee of (i) ten percent (10%) of the aggregate purchase price of the Units sold in this offering and (ii) warrants to purchase ten percent (10%) of the number of shares sold in this offering. In the case of the Minimum Offering, 31,250,000 Units, the Placement Agent will be issued warrants to purchase 3,125,000 shares of Common Stock at an exercise price of $0.08 per share and in the case of the Maximum Offering, 50,000,000 Units, the Placement Agent will be issued warrants to purchase 5,000,000 shares of Common Stock at an exercise price of $0.08 per share.

As required by FINRA pursuant to Rule 5110(g)(1), neither the Placement Agent’s Warrants nor any shares of common stock issued upon exercise of the Placement Agent’s 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.

Escrow Arrangements

Placement Agent and the Company shall instruct investors to deliver to Escrow Agent checks made payable to the order of "Signature Bank, as Escrow Agent for SANUWAVE Health, Inc.," or wire transfer to Signature Bank, 261 Madison Avenue, New York, New York 10016, ABA No. 026013576 for credit to Signature Bank, as Escrow Agent for SANUWAVE Health, Inc., Account No. 1502623709, in each case, with the name and address of the individual or entity making payment. In the event that any Investor's address is not provided to Escrow Agent by the Investor, then Placement Agent and/or Company agree to promptly provide Escrow Agent with such information in writing. The check or wire transfers shall be deposited into a non interest-bearing account at Signature Bank entitled SANUWAVE Health, Inc., Signature Bank, as Escrow Agent (the "Escrow Agent"). No investor funds will be accepted prior to effectiveness of the Registration Statement. After the Registration Statement is declared effective and prior to the closing date, all investor funds will be placed promptly, and in any event no later than noon Eastern Standard Time of the next business day following receipt, in escrow with the Escrow Agent in an escrow account established for the benefit of the investors. Prior to the closing date, the Escrow Agent will advise the Company whether the investors have deposited the requisite funds in the escrow account with the Escrow Agent. If the requisite funds have been deposited, the Company's transfer agent will deposit with The Depository Trust Company the securities to be credited to the respective accounts of the investors. Investor funds will be collected by the Company through the facilities of the Escrow Agent on the scheduled closing date. In the event that requisite investor funds are not received by the closing date, all funds deposited in the escrow account will promptly be returned in full.

Because there cannot be any assurance that Maximum Offering Amount will be sold in this offering, the actual total offering commissions, if any, are not presently determinable.

If we do not sell and receive payments for the Minimum Offering Amount prior to February 19, 2016, investor subscriptions will be returned without interest or deduction.

Our obligations to issue and sell the Units to the purchasers is subject to the conditions set forth in the subscription agreement, which may be waived by us at our discretion. A purchaser's obligation to purchase the shares of common stock and warrants is subject to the conditions set forth in the subscription agreement as well, which may also be waived.

We estimate the total offering expenses in this offering that will be payable by us, excluding the Placement Agent' fees, will be approximately $45,000 which include legal, accounting and printing costs, various other fees and reimbursement of the Placement Agent' expenses. Such fees and expense reimbursement to the Placement Agent total approximately $24,000 and are payable in addition to the commission-based compensation disclosed in the second paragraph of this Plan of Distribution.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agent agreement and the subscription agreement. A copy of the placement agent agreement and the form of subscription agreement with investors are included as exhibits to the Registration Statement of which this prospectus forms a part.

The Placement Agent may be deemed to be underwriters within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by them and any profit realized on the resale of the securities sold by them while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As underwriters, the Placement Agent would be required to comply with the Securities Act and the Securities Exchange Act of 1934, as amended, including without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent acting as principal.

Under these rules and regulations, the Placement Agent:

may not engage in any stabilization activity in connection with our securities; and

may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Lock-Up Agreements

Pursuant to certain "lock-up" agreements, (a) our executive officers and directors as of the pricing date of the offering, will agree, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any securities of the company without the prior written consent of the Placement Agent, for a period of 90 days from the date of the final prospectus of the offering, and (b) we, and any successor, will agree, subject to certain exceptions, not to for a period of 90 days from the date of the final prospectus of the offering (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our capital stock; (2) file or caused to be filed any registration statement with the SEC relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our capital stock, whether any such transaction described in (1), (2), or (3) above is to be settled by delivery of shares of our capital stock or such other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit, among other things, (1) the issuance by us of stock options pursuant to our existing stock incentive plans, or (2) the issuance of common stock upon the exercise of outstanding stock options and warrants.

Our Participation

Rule 3a4-1 sets forth those conditions under which a person associated with an issuer may participate in the offering of the issuer's securities and not be deemed to be a broker-dealer. Those conditions are as follows:

a. Our officers and directors are not subject to a statutory disqualification, as that term is defined in Section 3(a)(39) of the Act, at the time of their participation;

b. Our officers and directors will not be compensated in connection with their participation by the payment of commissions or other remuneration based either directly or indirectly on transactions in securities;

c. Our officers and directors are not, nor will they be at the time of their participationin the offering, an associated person of a broker-dealer; and

d. Our officers and directors meet the conditions of paragraph (a)(4)(ii) of Rule 3a4-1 of the Exchange Act, in that they (A) primarily perform, or intend primarily to perform at the end of the offering, substantial duties for or on behalf of our Company, other than in connection with transactions in securities; and (B) are not a broker or dealer, or been associated person of a broker or dealer, within the preceding twelve months; and (C) have not participated in selling and offering securities for any Issuer more than once every twelve months other than in reliance on Paragraphs (a)(4)(i) and (a)(4)(iii).

Certain of our affiliates may purchase Units in this offering on the same terms as they are offered and sold to the public.

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses will be approximately $45,000, all of which are payable by us.

Pricing of this Offering

The public offering price of the Units was determined by us. Factors considered in determining the prices and terms of the shares include:

- the history and prospects of companies in our industry;
- prior offerings of those companies;
- our prospects for developing and commercializing our products;
- our capital structure;
- an assessment of our management and their experience;
- general conditions of the securities markets at the time of the offering; and
- other factors as were deemed relevant.

Penny Stock

The SEC has adopted Rule 15g-9 which establishes the definition of a ”penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our Common Stock and cause a decline in the market value of our Common Stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock.

Offering by Selling Stockholders

We are registering the shares of Common Stock issued to the selling stockholders to permit the resale of these shares of Common Stock by the selling stockholders, from time to time, after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of Common Stock.

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 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%).