

SECURITIES AND EXCHANGE COMMISSION

FORM CORRESP

Correspondence

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FILER

**SANUWAVE Health, Inc.**

CIK: [1417663](#) | IRS No.: **201176000** | State of Incorporation: **NV** | Fiscal Year End: **1231**

Type: **CORRESP**

SIC: **3841** Surgical & medical instruments & apparatus

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May 16, 2013

**VIA EDGAR**

Securities and Exchange Commission  
100 F. Street, NE  
Washington, D.C. 20549

Attention: Amanda Ravitz  
Assistant Director

**Re: SANUWAVE Health, Inc.  
Registration Statement on Form S-1  
Filed March 29, 2013  
File No. 333-187625**

Dear Ms. Ravitz:

On behalf of SANUWAVE Health, Inc. (the “*Company*”), we are responding to the comments of the staff (the “*Staff*”) of the Securities and Exchange Commission (the “*Commission*”) contained in your letter dated April 17, 2013 with respect to the Company’s registration statement on Form S-1, File No. 333-187625 (the “*Registration Statement*”), filed with the Commission on the date referenced above. For those comments which the Staff has specifically informed us require amendments to documents previously filed with the Commission, we have filed such amended documents and note the same in our responses below. The Company’s responses below are numbered to correspond to the numbered paragraph in the Staff’s comment letter. For your convenience, we repeat in **bold** each of the Staff’s comments prior to each response.

**1. General**

**Please revise your filing to include all information except that which can be excluded by Securities Act Rule 430A. We note for example that you have not included the duration of the offering or the number of shares, warrants, or shares underlying the warrants to be offered.**

The Company has revised the prospectus contained in the Registration Statement to include additional information related to the terms of the offering, including the duration of the offering. With respect to the units to be offered (the “*Units*”), the offering price of the Units, the warrants which are a component of the Units and the exercise price of the warrants, and related information, the Company has updated the prospectus with an assumed offering price, and has, in turn, updated the other foregoing information in the prospectus which is dependent upon the offering price.

2. **Prospectus Summary, page 1**

**Please balance your summary by including disclosure of your liquidity situation, working capital deficit, accumulated deficit, the need for additional financing even if you sell all of the units in this offering, the expected cost of your supplemental Phase III clinical trial, the going concern opinion from your independent registered public accounting firm and length of time that your current liquidity will support your operations.**

In response to this comment by the Staff, the Company has amended the prospectus summary contained in the Registration Statement to include the required information. This information is contained in Amendment No. 1 to the Registration Statement, which is being filed with the Commission contemporaneously with this response letter. Below is the section of the prospectus summary which has been amended to include such information:

**Liquidity and Capital Resources**

The continuation of our business is dependent upon raising additional capital in the second quarter of 2013. As of March 31, 2013, we had cash and cash equivalents of \$671,027 and negative working capital of \$7,130,480. For the three months ended March 31, 2013 and 2012, the net cash used by operating activities was \$1,043,674 and \$1,490,445, respectively. We incurred a net loss of \$5,369,333 for the three months ended March 31, 2013 and a net loss of \$6,401,494 for the year ended December 31, 2012. Since inception, we have experienced recurring losses from operations and had an accumulated deficit of \$76,279,655 at March 31, 2013. As a result, our auditors have raised substantial doubts as to our ability to continue as a going concern.

On March 8, 2013, we completed a private placement to accredited investors of an aggregate \$2,000,000 of 18% Senior Secured Convertible Promissory Notes (Senior Secured Notes). The Senior Secured Notes begin to mature in May 2013 and we are working with the holders to extend the maturity through the second quarter of 2013. The Senior Secured Notes, as amended, will automatically convert to common stock if we raise \$4,000,000 or more in gross proceeds through a qualified financing (such as in this offering) and/or license agreement as defined in the Senior Secured Note agreements. If we do not raise at least \$4,000,000, the Senior Secured Notes will not automatically convert to common stock and will become due and payable.

We expect to raise up to \$600,000 through the issuance of unsecured promissory notes in May and June 2013 and/or amounts received through a subscription agreement with an affiliated shareholder. When combined with our cash and cash equivalents as of March 31, 2013 of \$671,027, we believe this will support our operations through the second quarter of 2013 and the expected completion of this offering. We expect our monthly use of cash will be approximately \$575,000 to \$625,000 as we devote substantial resources to the start of the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers by the end of the second quarter of 2013. We estimate the direct cost of the dermaPACE clinical trial will be approximately \$3,800,000 through 2014.

Even if we sell all of the Units offered in this offering, we will require additional capital to support the dermaPACE clinical trial and continue our operations within the next twelve months. 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

**3. Prospectus Summary, page 1**

**Please revise your summary to disclose the major deficiency letter you received from the FDA in December 2011.**

In response to this comment by the Staff, the Company has amended the prospectus summary contained in the Registration Statement to include the required information. This information is contained in Amendment No. 1 to the Registration Statement, which is being filed with the Commission contemporaneously with this response letter. Below is the section of the prospectus summary which has been amended to include such information:

**Product Overview**

*dermaPACE – Our lead product candidate*

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. We have identified and contracted with clinical study sites for participation in the clinical study. We held the investigator meeting for protocol training on May 10-11, 2013 and expect that patient enrollment will begin in the second quarter of 2013.

The dermaPACE device completed its pivotal Phase III, IDE trial in the United States for the treatment of diabetic foot ulcers in 2011 and a PMA Application was filed with the FDA in June 2011. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. In December 2011, we received a major deficiency letter from the FDA regarding the FDA's review of the dermaPACE PMA. The FDA issues a major deficiency letter to the applicant when the PMA lacks significant information necessary for the FDA to complete its review or to determine whether there is reasonable assurance that the device is safe and effective for its intended use.

In its December 2011 letter, the FDA cited, among other deficiencies, the dermaPACE study's failure to meet the study's primary endpoint of 100% wound closure compared with sham-control at the 12-week time point. Among the letter's recommendations to address the deficiency was for us to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. We evaluated the comments in the FDA's letter and after further analyses of the clinical data and informal, non-binding interaction with the FDA, we decided to conduct supplemental clinical work as discussed above.

4. **About this Offering, page 3**

**Please revise your filing prior to effectiveness to clarify whether you have amended your senior secured notes as contemplated in your disclosure on page 4.**

The Company has amended the Senior Secured Notes as contemplated in the Registration Statement, as originally filed on Form S-1. The language “We plan to have such notes amended prior to commencement of this offering” has been removed from each place in which it appeared in the prospectus, as reflected in Amendment No. 1 to the Registration Statement, being filed with the Commission contemporaneously with this response letter (although the Senior Secured Notes may be amended further, for the purpose of extending the maturity dates of such notes, as stated below). Although the language reflecting the amendment of the Senior Secured Notes has been updated throughout the prospectus contained in the Registration Statement, in specific response to the Staff’s comment, the updated language for the section entitled “About this Offering” is as follows:

*Use of proceeds* .....

We intend to use the net proceeds from the sale of shares by us primarily for expenses related to our dermaPACE clinical trial for treating diabetic foot ulcers in the United States and for other general corporate purposes.

We have outstanding an aggregate \$2,097,500 in principal and accrued interest on our 18% Senior Secured Convertible Promissory Notes, as amended (Senior Secured Notes), which begin to mature in May 2013. We are currently negotiating with the holders to extend the maturity through the second quarter of 2013. Subject to the condition that we raise at least \$4,000,000 in gross proceeds through this offering, the Senior Secured Notes will automatically convert into (i) common stock at a conversion price of \$0.20, and (ii) warrants to purchase the number of shares of common stock equal to the number of shares such holder would have received if it had invested in the offering an amount equal to the principal and interest on the note being converted. If we do not raise at least \$4,000,000 in gross proceeds through this offering the Senior Secured Notes will not automatically convert to common stock and they will become due and payable and we will use all or part of any net proceeds from this offering towards repayment of the Senior Secured Notes. See “Use of Proceeds” and “Description of Securities”.

5. **Plan of Distribution, page 28**

**We note your disclosure in the second paragraph of this section that you may engage registered broker-dealers in connection with this offering and on page F-6 that you have engaged an investment bank to assist you with raising capital. Please revise your filing to provide the information required under Regulation S-K Item 508.**

The Company has engaged Agincourt Ltd. to act as placement agent in the offering, on a “best efforts” basis. The prospectus contained in the Registration Statement has been revised to reflect the engagement of Agincourt Ltd., and, specifically, the section entitled “Plan of Distribution” contained in the Amendment No. 1 to the Registration Statement contains the following disclosure:

**Distribution**

We are offering up to \_\_\_\_\_ Units at a purchase price of \$ \_\_\_\_ per Unit, with each Unit consisting of one share of our common stock and a warrant to purchase up to an additional \_\_\_\_\_ share of our common stock at an exercise price of \$ \_\_\_\_ per share. The Units will separate immediately and the common stock and warrants will be issued separately and the common stock will trade separately.

We have engaged Agincourt, Ltd. (the “Placement Agent”) as the placement agent for this offering. The Placement Agent is not purchasing or selling any securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of Units, but will use its reasonable “best efforts” to sell all of the Units being offered. Because there is no minimum offering amount required as a condition to closing this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth herein.

Upon the closing of the offering, we will pay the Placement Agent a cash fee equal to 8.0% of the gross proceeds to us from the sale of the securities in the offering. We have also agreed to reimburse the Placement Agent for any out-of-pocket expenses it incurs in connection with the offering. Pursuant to the investment banking agreement, we retained Agincourt, Ltd. to act as our exclusive investment banker to perform the services set forth therein for a period of one year commencing on February 25, 2013, subject to the right of either party to terminate the agreement upon 30 days’ written notice.

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent would be required to comply with the requirements of the Securities Act of 1933, as amended, 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 shares of common stock and warrants to purchase shares of common stock by the Placement Agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; or (ii) 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 they have completed their participation in the distribution.

Our Agreement with the Placement Agent provides that we will indemnify the Placement Agent against specified liabilities, including liabilities under the Securities Act. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification for liabilities under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable.

This offering expires at 5:00 p.m. Eastern Time on September 30, 2013. The offering will terminate automatically prior to the expiration date, if the offering is fully subscribed. In addition, we may terminate the offering at any time prior to the expiration date.

Our obligations to issue and sell the securities offered hereby to the purchasers is subject to the conditions set forth in a securities purchase agreement, which may be waived by us at our discretion. A purchaser’s obligation to purchase the securities is subject to the conditions set forth in a securities purchase agreement as well, which may also be waived by the purchaser.

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

**6. Security Ownership of Certain Beneficial Owners and Management, page 79**

We note your disclosure on page 81 that Mr. Richardson serves as the managing partner of Prides Capital, an affiliate of Prides Capital Fund I which owns 45.7% of your outstanding shares of common stock. Please disclose the beneficial owner of the shares held by Prides Capital Fund I. If Mr. Richardson is the beneficial owner of those shares, please revise your table on page 79 to aggregate Pride Capital Fund I's ownership with Mr. Richardson's ownership. We also note your disclosure that Mr. Nemelka serves as managing principal of NightWatch Capital Advisors, an affiliate of NightWatch Capital Partners II which owns 9.7% of your shares. Similarly, please disclose the beneficial owner of the shares held by NightWatch Capital Partners II. If Mr. Nemelka is the beneficial owner of those shares, please revise your table on page 79 to aggregate NightWatch Capital Partners II's ownership with that of Mr. Nemelka's. Refer to Instruction 2 of Item 403 of Regulation S-K and Exchange Act Rule 13d-3(c).

In response to this comment by the Staff, the Company has amended the information in the section of the prospectus entitled "Security Ownership of Certain Beneficial Owners and Management" contained in the Registration Statement, and such amendments are reflected in Amendment No. 1 to the Registration Statement being filed with the Commission contemporaneously with this response letter. The Security Ownership of Certain Beneficial Owners and Management table, as amended, is reproduced below:

Name of Beneficial Owner <sup>(1)</sup>	Number of Shares Beneficially Owned <sup>(2)</sup>	Percent of Shares Outstanding
Joseph Chiarelli <sup>(3)</sup>	375,000	1.7%
Barry J. Jenkins <sup>(4)</sup>	480,003	2.2%
Kevin A. Richardson, II <sup>(5)</sup>	12,307,914	52.4%
John F. Nemelka <sup>(6)</sup>	2,147,202	9.8%
<b>5% Beneficial Owner:</b>		
David N. Nemelka <sup>(7)</sup>	5,048,510	19.6%
Christopher M. Cashman <sup>(8)</sup>	3,936,259	15.6%
Prides Capital Fund I, LP <sup>(9)</sup>	10,520,077	45.4%
NightWatch Capital Partners II, LP <sup>(10)</sup>	2,108,369	9.6%
All directors and executive officers as a group (4 persons)	15,310,120	62.7%

(1) Unless otherwise noted, each beneficial owner has the same address as us.

(2) Applicable percentage ownership is based on 21,726,536 shares of common stock outstanding as of May 13, 2013, "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 May 13, 2013. Unless otherwise indicated, all of the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.

- (3) Consist of options to purchase up to 375,000 shares of common stock.
- (4) Includes options to purchase up to 274,253 shares of common stock and warrants to purchase up to 3,508 shares of common stock.
- (5) Includes options to purchase up to 38,333 shares of common stock and promissory notes convertible into 309,000 shares of common stock. In addition, this amount includes 9,081,989 shares of common stock and warrants to purchase 1,438,088 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.
- (6) Includes options to purchase up to 38,333 shares of common stock. In addition, this amount includes 1,904,145 shares of common stock and warrants to purchase 204,224 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.
- (7) Based solely on information contained in filings on Schedule 13D, as amended, and on Form 4s, made with the SEC by the reporting person, and on records of the Company. Includes a subscription agreement to purchase 3,600,000 shares of common stock at \$0.25 per share no later than May 27, 2014 and warrants to purchase up to 443,510 shares of common stock. The principal address of David N. Nemelka is 2662 Stonebury Loop Road, Springville, UT 84663.
- (8) Includes options to purchase up to 3,460,686 shares of common stock and warrants to purchase up to 8,816 shares of common stock. Mr. Cashman resigned as President, Chief Executive Officer, and as a Director effective November 7, 2012.
- (9) 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 1,438,088 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 (5).
- (10) Based solely on information contained in filings on Schedule 13D, as amended, made with the SEC by the reporting person and of records of the Company. Includes warrants to purchase 204,224 shares of common stock. The principal business address of NightWatch Capital Partners II, LP is 5314 River Run Drive, Suite 350, Provo, UT 84604. John F. Nemelka has voting and dispositive power over the securities. See footnote (6).

7. **Security Ownership of Certain Beneficial Owners and Management, page 79**

**Please reconcile the ownership figures disclosed in the first paragraph of page 23 with those in your table on page 79.**

In response to this comment by the Staff, the Company has changed the ownership information disclosed in the first paragraph of page 23 contained in the Registration Statement, and such amendments are reflected in Amendment No. 1 to the Registration Statement being filed with the Commission contemporaneously with this response letter, as follows:

***Prides Capital and NightWatch Capital control and may continue to control us and may have conflicts of interest with us or you in the future.***

As of May 13, 2013, Prides Capital owned 45.4% of our outstanding common stock and Kevin A. Richardson, II, who is managing partner of Prides Capital, beneficially owned 52.4% of our outstanding common stock. In addition, as of May 13, 2013, NightWatch Capital owned 9.6% of our outstanding common stock and John F. Nemelka, who is managing partner of Nightwatch Capital, beneficially owned 9.8% of our outstanding common stock. Mr. Richardson was appointed by Prides Capital and Mr. John Nemelka was appointed by NightWatch Capital to serve on our board of directors. For as long as Prides Capital and NightWatch Capital own a majority of our shares of common stock, they will be able to control the election of all of the members of our board of directors and control the vote of shareholders on other matters. For as long as they own a significant percentage of our outstanding stock, even if less than a majority, Prides Capital and NightWatch Capital will be able to control and exercise significant influence over our business affairs, including the general strategic direction of our business, the incurrence of indebtedness by us, the issuance of any additional equity securities, the repurchase of equity securities and the payment of dividends, and will have the power to determine or significantly influence the outcome of matters submitted to a vote of our shareholders, including mergers, consolidations, sales or dispositions of assets, reductions in share capital, other business combinations and amendments to our articles of incorporation. Prides Capital and NightWatch Capital may take actions with which you do not agree, including actions that delay, defer or prevent a change in control of our company or that could adversely affect the market price of our common stock. In addition, they may take other actions that might be favorable to them, but not favorable to us or our other shareholders. Also, if either Prides Capital or NightWatch Capital sells all or a portion of its interest in us, it may cause the price of our common stock to decrease.

8. **Item 16. Exhibits and Financial Statement Schedules, page II-4**

**Please file an opinion from counsel on the legality of the securities being offered.**

In response to this comment by the Staff, the Company has attached an opinion from counsel as Exhibit 5.1 to Amendment No. 1 to the Registration Statement being filed with the Commission contemporaneously with this response letter.

\* \* \*

The Company would appreciate your earliest consideration of this response. If you have any questions or require any additional information with respect to any matters discussed in this letter, please contact the undersigned at (404) 815.3634 (telephone) or (404) 685.6934 (facsimile). Thank you.

Very truly yours,

/s/John C. Ethridge, Jr.

John C. Ethridge, Jr.

cc: Brian Soares  
Tim Buchmiller  
Securities and Exchange Commission  
Staff Attorney

Joseph Chiarelli  
SANUWAVE Health, Inc.  
Chief Executive Officer

Barry Jenkins  
SANUWAVE Health, Inc.  
Chief Financial Officer