

SANUWAVE Health, Inc.  
Form 10-Q  
November 12, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2014**

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

**For the transition period from \_\_\_\_\_ to**

**Commission File Number 000-52985**

**SANUWAVE Health, Inc.**

(Exact name of registrant as specified in its charter)

|  |                     |
|--|---------------------|
| <b>Nevada</b>                          | <b>20-1176000</b>   |
| (State or other jurisdiction of        | (I.R.S. Employer    |
| incorporation or organization)         | Identification No.) |
| <b>11475 Great Oaks Way, Suite 150</b> | <b>30022</b>        |

**Alpharetta, GA**

(Address of principal executive offices) (Zip Code)

**(770) 419-7525**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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 definition 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

(Do not check if a smaller reporting company)

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

As of November 7, 2014, there were issued and outstanding 50,706,519 shares of the registrant's common stock, \$0.001 par value.

**SANUWAVE Health, Inc.**

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### Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of SANUWAVE Health, Inc. and its subsidiaries (“SANUWAVE” or the “Company”) contains forward-looking statements. All statements in this Quarterly Report on Form 10-Q, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company’s future financial results, clinical trial results, regulatory approvals, 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. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission, specifically the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 31, 2014 and in the Company’s Quarterly Reports on Form 10-Q. Other risks and uncertainties are and will be disclosed in the Company’s prior and future Securities and Exchange Commission (the “SEC”) filings. These and many other factors could affect the Company’s future financial condition and operating results and could cause actual results to differ materially from expectations based on forward-looking statements made in this document or elsewhere by the Company or on its behalf. The Company undertakes no obligation to revise or update any forward-looking statements. The following information should be read in conjunction with the financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 31, 2014.

*Except as otherwise indicated by the context, references in this Quarterly Report on Form 10-Q to “we,” “us” and “our” are to the consolidated business of the Company.*

**PART I — FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS (UNAUDITED)**

## SANUWAVE HEALTH, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

|  | September<br>30,<br>2014 | December<br>31,<br>2013 |
|--|--------------------------|-------------------------|
| <b>ASSETS</b>  |                          |                         |
| <b>CURRENT ASSETS</b>  |                          |                         |
| Cash and cash equivalents  | \$4,687,222              | \$182,315               |
| Accounts receivable - trade, net of allowance for doubtful accounts of \$48,044 in 2014 and \$43,282 in 2013 | 94,954                   | 139,736                 |
| Inventory  | 257,962                  | 246,006                 |
| Prepaid expenses   | 162,306                  | 75,020                  |
| <b>TOTAL CURRENT ASSETS</b>  | <b>5,202,444</b>         | <b>643,077</b>          |
| <br><b>PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 3)</b>                           | <br><b>8,814</b>         | <br><b>13,267</b>       |
| <br><b>OTHER ASSETS</b>  | <br><b>11,228</b>        | <br><b>11,444</b>       |
| <br><b>INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 4)</b>                                | <br><b>690,202</b>       | <br><b>920,269</b>      |
| <b>TOTAL ASSETS</b>  | <b>\$5,912,688</b>       | <b>\$1,588,057</b>      |
| <br><b>LIABILITIES</b>   |                          |                         |
| <b>CURRENT LIABILITIES</b>   |                          |                         |
| Accounts payable   | \$402,674                | \$935,028               |
| Accrued expenses (Note 5)  | 359,218                  | 863,572                 |
| Accrued employee compensation  | 117,700                  | 140,102                 |
| Interest payable, related parties (Note 7)   | 81,864                   | 163,729                 |
| Notes payable, related parties (Note 7)  | 5,372,743                | -                       |
| Convertible promissory note (Note 9)   | -                        | 147,775                 |
| Promissory notes   | -                        | 89,038                  |
| Capital lease payable  | -                        | 3,951                   |
| <b>TOTAL CURRENT LIABILITIES</b>   | <b>6,334,199</b>         | <b>2,343,195</b>        |
| <br><b>NON-CURRENT LIABILITIES</b>   |                          |                         |

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|   |                    |                     |
|---|--------------------|---------------------|
| Notes payable, related parties (Note 7)   | -                  | 5,372,743           |
| <b>TOTAL LIABILITIES</b>  | <b>6,334,199</b>   | <b>7,715,938</b>    |
| <br><b>COMMITMENTS AND CONTINGENCIES (Note 12)</b>  | <br>-              | <br>-               |
| <br><b>STOCKHOLDERS' EQUITY (DEFICIT)</b>   |                    |                     |
| PREFERRED STOCK, SERIES A CONVERTIBLE, par value \$0.001, 6,175 shares authorized; 6,175 shares issued and outstanding (Note 10)                    | 6                  | -                   |
| <br>PREFERRED STOCK - UNDESIGNATED, par value \$0.001, 4,993,825 shares authorized; no shares issued and outstanding                                | <br>-              | <br>-               |
| <br>COMMON STOCK, par value \$0.001, 150,000,000 shares authorized; 50,706,519 and 37,984,182 issued and outstanding in 2014 and 2013, respectively | <br>50,707         | <br>37,984          |
| <br>ADDITIONAL PAID-IN CAPITAL  | <br>87,496,831     | <br>76,037,490      |
| <br>ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)   | <br>(8,503 )       | <br>6,688           |
| <br>ACCUMULATED DEFICIT   | <br>(87,960,552)   | <br>(82,210,043)    |
| <b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>   | <b>(421,511 )</b>  | <b>(6,127,881 )</b> |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>   | <b>\$5,912,688</b> | <b>\$1,588,057</b>  |

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

## SANUWAVE HEALTH, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

|   | Three<br>Months<br>Ended<br>September<br>30,<br>2014 | Three<br>Months<br>Ended<br>September<br>30,<br>2013 | Nine<br>Months<br>Ended<br>September<br>30,<br>2014 | Nine Months<br>Ended<br>September<br>30,<br>2013 |
|---|--|--|---|--|
| REVENUE   | \$227,492  | \$148,421  | \$610,705   | \$510,272  |
| COST OF REVENUE   | 68,077   | 29,467   | 149,813   | 109,061  |
| GROSS PROFIT  | 159,415  | 118,954  | 460,892   | 401,211  |
| OPERATING EXPENSES  |  |  |   |  |
| Research and development  | 708,304  | 775,717  | 2,486,801   | 1,744,935  |
| General and administrative  | 780,115  | 1,151,709  | 2,774,828   | 3,160,749  |
| Depreciation  | 3,827  | 4,854  | 13,312  | 14,836   |
| Amortization  | 76,689   | 76,689   | 230,067   | 230,067  |
| TOTAL OPERATING EXPENSES  | 1,568,935  | 2,008,969  | 5,505,008   | 5,150,587  |
| OPERATING LOSS  | (1,409,520 )   | (1,890,015 )   | (5,044,116 )  | (4,749,376 )                                     |
| OTHER INCOME (EXPENSE)  |  |  |   |  |
| Loss on embedded conversion feature of Senior Secured Notes (Note 6)        | -  | (964,813 )   | -   | (2,373,813 )                                     |
| Loss on extinguishment of Senior Secured Notes (Note 6)                     | -  | (1,073,572 )   | -   | (1,073,572 )                                     |
| Accretion of interest and interest expense on Senior Secured Notes (Note 6) | -  | (421,060 )   | -   | (2,178,390 )                                     |
| Interest expense, net   | (79,955 )  | (88,772 )  | (700,085 )  | (256,472 )                                       |
| Gain on sale of fixed assets  | -  | -  | -   | 7,500  |
| Gain (loss) on foreign currency exchange                                    | (3,430 )   | 1,442  | (6,308 )  | (331 )   |
| TOTAL OTHER INCOME (EXPENSE)  | (83,385 )  | (2,546,775 )   | (706,393 )  | (5,875,078 )                                     |
| LOSS BEFORE INCOME TAXES  | (1,492,905 )   | (4,436,790 )   | (5,750,509 )  | (10,624,454 )                                    |
| INCOME TAX EXPENSE  | -  | -  | -   | -  |
| NET LOSS  | (1,492,905 )   | (4,436,790 )   | (5,750,509 )  | (10,624,454 )                                    |
| OTHER COMPREHENSIVE INCOME (LOSS)   |  |  |   |  |

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|  |                |                |                |                 |
|--|----------------|----------------|----------------|-----------------|
| Foreign currency translation adjustments | (10,210 )      | (1,829 )       | (15,191 )      | (5,804 )        |
| TOTAL COMPREHENSIVE LOSS                 | \$(1,503,115 ) | \$(4,438,619 ) | \$(5,765,700 ) | \$(10,630,258 ) |

LOSS PER SHARE:

|                              |           |           |           |           |
|------------------------------|-----------|-----------|-----------|-----------|
| Net loss - basic and diluted | \$(0.03 ) | \$(0.14 ) | \$(0.12 ) | \$(0.43 ) |
|------------------------------|-----------|-----------|-----------|-----------|

|   |            |            |            |            |
|---|------------|------------|------------|------------|
| Weighted average shares outstanding - basic and diluted | 50,706,519 | 31,874,479 | 46,258,912 | 24,969,972 |
|---|------------|------------|------------|------------|

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



## SANUWAVE HEALTH, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

|  | Nine<br>Months<br>Ended<br>September<br>30,<br>2014 | Nine Months<br>Ended<br>September<br>30,<br>2013 |
|--|---|--|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |   |  |
| Net loss   | \$(5,750,509 )                                      | \$(10,624,454)                                   |
| Adjustments to reconcile net loss to net cash used by operating activities             |   |  |
| Amortization   | 230,067   | 230,067  |
| Depreciation   | 13,312  | 14,836   |
| Change in allowance for doubtful accounts  | 4,762   | 352  |
| Stock-based compensation - employees, directors and advisors                           | 91,788  | 683,382  |
| Stock issued for consulting services   | 743,150   | 751,587  |
| Accrued interest on 18% Convertible Promissory Notes                                   | 7,168   | -  |
| Accretion of interest on warrants issued concurrent with a convertible promissory note | 339,864   | -  |
| Loss on embedded conversion feature of Senior Secured Notes                            | -   | 2,373,813  |
| Accretion of interest and accrued interest on Senior Secured Notes                     | -   | 2,178,390  |
| Loss on extinguishment of Senior Secured Notes   | -   | 1,073,572  |
| Gain on sale of property and equipment   | -   | (7,500 )   |
| Changes in assets - (increase)/decrease  |   |  |
| Accounts receivable - trade  | 40,020  | 21,554   |
| Inventory  | (11,956 )   | 48,907   |
| Prepaid expenses   | (87,286 )   | 39,735   |
| Other  | 216   | (26 )  |
| Changes in liabilities - increase/(decrease)   |   |  |
| Accounts payable   | (532,354 )  | (165,858 )                                       |
| Accrued expenses   | (504,354 )  | 111,725  |
| Accrued employee compensation  | (22,402 )   | (106,426 )                                       |
| Interest payable, related parties  | (81,865 )   | -  |
| Promissory notes - accrued interest  | (21,813 )   | 1,450  |
| <b>NET CASH USED BY OPERATING ACTIVITIES</b>   | <b>(5,542,192 )</b>                                 | <b>(3,374,894 )</b>                              |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |   |  |
| Sale of property and equipment   | -   | 7,500  |
| Purchase of property and equipment   | (8,859 )  | -  |
| <b>NET CASH PROVIDED (USED) BY INVESTING ACTIVITIES</b>                                | <b>(8,859 )</b>                                     | <b>7,500</b>                                     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |   |  |

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|  |               |              |
|--|---------------|--------------|
| Proceeds from 2014 Private Placement, net                    | 8,562,500     | -            |
| Proceeds from sale of capital stock - subscription agreement | 900,000       | 75,000       |
| Proceeds from 18% Convertible Promissory Notes               | 815,000       | -            |
| Proceeds from convertible promissory notes, net              | 325,000       | -            |
| Proceeds from employee stock option exercise                 | 12,600        | 37,917       |
| Proceeds from subscriptions payable for Senior Secured Notes | -             | 1,570,000    |
| Proceeds from public offering, net                           | -             | 1,517,450    |
| Proceeds from private placement                              | -             | 405,000      |
| Proceeds from promissory notes                               | -             | 360,000      |
| Payments of principal on convertible promissory notes        | (450,000 )    | -            |
| Payments of principal on promissory notes                    | (90,000 )     | (325,000 )   |
| Payments of principal on capital lease                       | (3,951 )      | (3,664 )     |
| NET CASH PROVIDED BY FINANCING ACTIVITIES                    | 10,071,149    | 3,636,703    |
| <br>EFFECT OF EXCHANGE RATES ON CASH                         | <br>(15,191 ) | <br>(5,804 ) |
| <br>NET INCREASE IN CASH AND CASH EQUIVALENTS                | <br>4,504,907 | <br>263,505  |
| <br>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD           | <br>182,315   | <br>70,325   |
| CASH AND CASH EQUIVALENTS, END OF PERIOD                     | \$4,687,222   | \$333,830    |
| <br>SUPPLEMENTAL INFORMATION                                 |               |              |
| Cash paid for interest, related parties                      | \$325,804     | \$242,904    |

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

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**1. Nature of the Business**

SANUWAVE Health, Inc. and subsidiaries (the “Company”) is a shockwave technology company using a patented system of noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. The Company’s 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. The Company’s lead regenerative product in the United States is the demaPACE® device, which is in a supplemental Phase III clinical study for treating diabetic foot ulcers with possible FDA approval in 2016, subject to submission of satisfactory clinical study results.

The Company’s portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body’s normal healing processes and regeneration. The Company intends to apply its Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. Revenue is from sales of the European Conformity Marking (“CE Mark”) devices and accessories in Europe, Canada, Asia and Asia/Pacific.

In addition, there are license/partnership opportunities for the Company’s shockwave technology for non-medical uses, including energy, water, food and industrial markets.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and footnotes required by United States generally accepted accounting principles for complete financial statements. The financial information as of September 30, 2014 and for the three and

nine months ended September 30, 2014 and 2013 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2014 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2014.

The condensed consolidated balance sheet at December 31, 2013 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements.

**Financial condition**

Since inception in 2005, the Company's operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2014, the Company had cash and cash equivalents totaling \$4,687,222 and negative working capital of \$1,131,755. For the nine months ended September 30, 2014 and 2013, the net cash used by operating activities was \$5,542,192 and \$3,374,894, respectively. Since inception, the Company has experienced recurring losses from operations and had an accumulated deficit of \$87,960,552 at September 30, 2014.

The Company does not currently generate significant recurring revenue and will require additional capital in the second half of 2015 to obtain FDA approval for the dermaPACE in 2016, assuming positive clinical study results. Although no assurances can be given, management of the Company believes that existing capital resources should enable the Company to fund operations into the third quarter of 2015. The Company's unsecured Notes Payable, Related Parties, which total \$5,372,743 at September 30, 2014, are due on August 1, 2015.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**2. Summary of Significant Accounting Policies (continued)**

The continuation of the Company's business is dependent upon raising additional capital in the second half of 2015 to fund operations and repay the Notes Payable, Related Parties or amend the note terms to extend the notes and/or consider other non-cash repayment options. Management's plans are to obtain additional capital in 2015 through investments by strategic partners in specific clinical indications or market opportunities, which may include strategic partnerships or licensing arrangements.

In addition, the Company may raise capital through the conversion of outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, or by selling all or a portion of the Company's assets (or some combination of the foregoing). If these efforts are unsuccessful, the Company may be forced to seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing shareholders. Although no assurances can be given, management of the Company believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for the Company to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

**Significant Accounting Policies**

For further information and a summary of significant accounting policies, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014.

**Recently Issued Accounting Standards**

New accounting pronouncements are issued by the Financial Standards Board ("FASB") or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies. The Company does not

expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company's results of operations, financial position or cash flow.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on the consolidated financial statements and has not yet determined the method by which the Company will adopt the standard in 2017.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**3. Property and equipment**

Property and equipment consists of the following:

|                               | September<br>30,<br>2014 | December<br>31,<br>2013 |
|-------------------------------|--------------------------|-------------------------|
| Machines and equipment        | \$ 240,295               | \$ 233,793              |
| Office and computer equipment | 173,761                  | 171,404                 |
| Software                      | 41,872                   | 41,872                  |
| Furniture and fixtures        | 22,447                   | 22,447                  |
| Other assets                  | 2,446                    | 2,446                   |
| Total                         | 480,821                  | 471,962                 |
| Accumulated depreciation      | (472,007)                | (458,695)               |
| Net property and equipment    | \$ 8,814                 | \$ 13,267               |

The aggregate depreciation related to property and equipment charged to operations was \$3,827 and \$4,854 for the three months ended September 30, 2014 and 2013, respectively, and \$13,312 and \$14,836 for the nine months ended September 30, 2014 and 2013, respectively.

**4. Intangible assets**

Intangible assets consist of the following:

| September<br>30,<br>2014 | December<br>31,<br>2013 |
|--------------------------|-------------------------|
|--------------------------|-------------------------|

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|                               |             |             |
|-------------------------------|-------------|-------------|
| Patents, at cost              | \$3,502,135 | \$3,502,135 |
| Less accumulated amortization | (2,811,933) | (2,581,866) |
| Net intangible assets         | \$690,202   | \$920,269   |

The aggregate amortization charged to operations was \$76,689 for the three months ended September 30, 2014 and 2013, and \$230,067 for the nine months ended September 30, 2014 and 2013.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**5. Accrued expenses**

Accrued expenses consist of the following:

|                                   | September<br>30,<br>2014 | December<br>31,<br>2013 |
|-----------------------------------|--------------------------|-------------------------|
| Accrued executive severance       | \$ 100,000               | \$ 400,000              |
| Accrued clinical study expenses   | 68,801                   | 188,927                 |
| Accrued consultants               | 68,800                   | 58,000                  |
| Accrued audit and tax preparation | 64,125                   | 91,000                  |
| Accrued legal professional fees   | 13,600                   | 29,500                  |
| Accrued board of directors fees   | 12,000                   | 37,333                  |
| Accrued other                     | 31,892                   | 58,812                  |
|                                   | <b>\$ 359,218</b>        | <b>\$ 863,572</b>       |

**6. 18% Senior secured convertible promissory notes**

During the period from November 2012 through March 8, 2013, the Company entered subscriptions payable for 18% senior secured convertible promissory notes (the “Senior Secured Notes”) from select accredited investors. The Company completed the offering and issued an aggregate \$2,000,000 in Senior Secured Notes on March 8, 2013.

The Senior Secured Notes had a six month term from the subscription date and the note holders could convert into Company common stock at anytime during the term at a conversion price of \$0.20 per share. Upon the consummation of a qualified financing and/or technology license, as defined in the Senior Secured Note agreements, as amended, of \$4,000,000 or more by the Company, the principal and interest on the Senior Secured Notes would automatically convert into Company common stock equal to the lower of (i) the Company common stock issued in the qualified financing and/or technology license, reduced by a discount of 20%, and (ii) \$0.20 per share. The note holders would also receive, if any were issued, warrants or any other securities issued in a qualified financing and/or technology license on similar terms to the qualified financing and/or technology license. The Senior Secured Notes were secured

by the tangible and intangible assets of the Company.

The conversion feature embedded in the Senior Secured Notes was accounted for as a derivative liability and resulted in the creation at issuance of a discount to the carrying amount of the debt in the amount of \$2,000,000, which was amortized as additional interest expense using the straight-line method over the term of the Senior Secured Notes (the Company determined that using the straight-line method of amortization did not yield a materially different amortization schedule than the effective interest method). The amount of the fair value of the embedded conversion feature in the Senior Secured Notes of \$4,908,000, at the date of issuance, less the debt discount, totaled \$2,908,000 and was recorded in the “loss on embedded conversion feature of Senior Secured Notes” in the accompanying consolidated statements of comprehensive loss. Subsequent fair value adjustments of the embedded conversion feature of a loss of \$829,000 at March 31, 2013, a gain of (\$2,328,000) at June 30, 2013 and a loss of \$964,813 at July 31, 2013 (the date of extinguishment – see below) are also included in this financial statement caption.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**6. 18% Senior secured convertible promissory notes (continued)**

On July 31, 2013, all of the holders of the Senior Secured Notes voluntarily converted all of the outstanding principal and interest of the Senior Secured Notes into Company common stock. The aggregate outstanding amount of principal and interest on the Senior Secured Notes at July 31, 2013 of \$2,186,906 was converted into 10,934,533 shares of Company common stock at the conversion price of \$0.20 per share - the market price at the time the subscription agreement was written - pursuant to the Senior Secured Note agreements. In return for the holders' voluntarily converting the outstanding Senior Secured Notes on or before July 31, 2013, the Company agreed to issue to the holders warrants to purchase an aggregate total of 1,988,095 shares of Company common stock (the "Class H Warrants"). The Class H Warrants have an exercise price of \$0.80 per share and are exercisable during the five-year period beginning on the date of issuance. In July 2013, the Company recorded a loss from extinguishment of debt of \$1,073,572, which was the estimated fair value of the warrants issued to the holders on the date of exchange calculated using the Black-Scholes pricing model using the following primary inputs of: (i) \$0.60 closing stock price on the date of grant, (ii) the expected time the warrants will be outstanding of five-years, (iii) estimated discount rate of 1.38%, and (iv) expected volatility of 149% based on historical data from companies similar in size and value to the Company.

Kevin A. Richardson, II, chairman of the board of directors and Co-Chief Executive Officer of the Company, converted an aggregate balance of \$64,500 of the Senior Secured Notes and received 322,500 shares of Company common stock and 58,635 Class H Warrants in the foregoing transaction.

Accrued interest expense on the Senior Secured Notes, including amortization of the debt discount, totaled \$421,060 for the three months ended September 30, 2013, and \$2,178,390 for the nine months ended September 30, 2013.

**7. Notes payable, related parties**

The notes payable, related parties consist of the following:

|  | September<br>30,<br>2014 | December<br>31,<br>2013 |
|--|--------------------------|-------------------------|
| Notes payable, unsecured, payable to HealthTronics, Inc., a shareholder of the Company |                          |                         |
| Current portion  | \$5,372,743              | \$-                     |
| Non-current portion  | -                        | 5,372,743               |
| Total  | \$5,372,743              | \$5,372,743             |

The notes payable, related parties were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. The notes payable, related parties bear interest at 6% per annum. Quarterly interest through June 30, 2010, was accrued and added to the principal balance. Interest is paid quarterly in arrears beginning September 30, 2010. All remaining unpaid accrued interest and principal is due August 1, 2015. Accrued interest currently payable totaled \$81,864 and \$163,729 at September 30, 2014 and December 31, 2013, respectively.

Interest expense on notes payable to related parties totaled \$81,864 for the three months ended September 30, 2014 and 2013, and \$243,940 and \$242,903 for the nine months ended September 30, 2014 and 2013, respectively.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**8. Income taxes**

The Company files income tax returns in the United States federal jurisdiction and various state and foreign jurisdictions. The Company is no longer subject to United States federal and state and non-United States income tax examinations by tax authorities for years before 2006.

At September 30, 2014, the Company had federal net operating loss (“NOL”) carryforwards of \$59,355,168 for tax years through the year ended December 31, 2013, that will begin to expire in 2025. The use of deferred tax assets, including federal net operating losses, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109), the Company’s management believes that there is not sufficient evidence at September 30, 2014 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2014. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including NOL carryforwards.

The Company’s ability to use its NOL carryforwards could be limited and subject to annual limitations. In connection with future offerings, the Company may realize a “more than 50% change in ownership” which could further limit its ability to use its NOL carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which NOL carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take advantage of all or portions of its NOL carryforwards for federal income tax purposes.

**9. Equity transactions**

**2014 Private Placement**

On March 17, 2014, in conjunction with a private placement of securities (the “2014 Private Placement”) with institutional and select accredited investors, the Company issued an aggregate total of 6,210,000 shares of common

stock and 6,175 shares of preferred stock (the “Series A Convertible Preferred Stock”) for an aggregate total purchase price of \$9,280,000. Each share of Series A Convertible Preferred Stock is convertible into 2,000 shares of common stock at the option of the holder. The proceeds received by the Company were \$8,562,500, net of offering costs of \$717,500.

The Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 23,200,000 warrants (the “Series A Warrants”) to purchase shares of common stock at an exercise price of \$0.50 per share. Each Series A Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after five years.

In addition, the Company, in connection with the 2014 Private Placement, issued to the investors an aggregate total of 13,920,000 warrants (the “Series B Warrants”) to purchase shares of common stock at an exercise price of \$1.50 per share. Each Series B Warrant represents the right to purchase one share of Common Stock. The warrants vested upon issuance and expire after one year.

Pursuant to the terms of a registration rights agreement that the Company entered with the investors in connection with the 2014 Private Placement, the Company filed a registration statement with the SEC in April 2014 that covers the shares of common stock and the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock and exercise of the Series A Warrants and Series B Warrants issued to the investors in the 2014 Private Placement. The registration statement was declared effective by the SEC on May 6, 2014.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**9. Equity transactions (continued)**

Kevin A. Richardson, II, chairman of the board of directors of the Company and Co-Chief Executive Officer; Joseph Chiarelli, the former Chief Executive Officer of the Company; and, Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, were purchasers in the 2014 Private Placement of \$50,000, \$40,000 and \$50,000, respectively.

At the closing of the 2014 Private Placement, the Company paid Newport Coast Securities, Inc., the placement agent for the private placement, and Oppenheimer & Co. Inc., the former placement agent, cash compensation based on the gross proceeds of the private placement and 696,000 Series A Warrants and 417,600 Series B Warrants.

**18% Convertible Promissory Notes**

During the period January 24, 2014 through March 7, 2014, the Company entered into subscriptions payable for 18% convertible promissory notes, as amended, (the "18% Convertible Promissory Notes") from selected accredited investors. Up to \$1,000,000 aggregate principal amount of 18% Convertible Promissory Notes were offered by the Company. The Company completed the offering and issued an aggregate \$815,000 in convertible notes in March 2014. Michael N. Nemelka, the brother of a member of the Company's board of directors and an existing shareholder of the Company, purchased \$110,000 of the convertible notes.

The 18% Convertible Promissory Notes had a nine month term from the subscription date and the note holders could convert into Company common stock at anytime during the term at \$0.55 per share. Upon the consummation of a qualified financing, as defined in the convertible note agreements, of \$1,000,000 or more by the Company, the principal and interest on the 18% Convertible Promissory Notes would convert into Company common stock equal to the lower of (i) the Company common stock issued in the qualified financing, and (ii) \$0.55 per share. The note holders would also receive, if any were issued, warrants or any other security issued in a qualified financing on similar terms to the qualified financing. The 18% Convertible Promissory Notes were unsecured.

The 2014 Private Placement was a qualified financing as defined in the 18% Convertible Promissory Notes. As such, on March 17, 2014, in conjunction with the 2014 Private Placement discussed above, the 18% Convertible Promissory Notes, with an aggregate outstanding principal and accrued interest balance of \$822,168, were automatically converted and the holders received in the aggregate 1,644,337 shares of common stock, 2,055,421 Series A Warrants, and 1,233,252 Series B Warrants.

**Subscription agreement**

On November 27, 2012, the Company and David N. Nemelka (the “Subscriber”), the brother of a member of the Company’s board of directors, entered into a subscription agreement (the “Subscription Agreement”) whereby the Subscriber agreed to purchase from the Company, and the Company has agreed to sell and issue, a total of 4,000,000 shares of the Company’s unregistered common stock at a purchase price equal to \$0.25 per share, for an aggregate sales price of \$1,000,000 (the “Purchase Price”). The shares are subject to piggy-back registration rights if the Company files a registration statement for an offering of securities.

The Purchase Price was payable to the Company as follows: (i) \$50,000 on or before January 31, 2013; (ii) \$50,000 on or before February 15, 2013; and (iii) the balance of \$900,000 on or before May 27, 2014 (the “Outside Due Date”). The Subscriber could make payments of the Purchase Price at his discretion in minimum installments of \$100,000 each, until the Outside Due Date.

In the event that at any time after February 15, 2013, the Company’s total available cash should be less than \$100,000, the Subscriber would, upon demand of the Company, pay to the Company \$100,000 of the then outstanding balance of the Purchase Price, which payment would be due within 30 days of the demand. There was no limit on the number of demands that the Company could make pursuant to this provision of the Subscription Agreement, provided, however, that in no event could the Company provide more than one notice of demand for payment in any 30 day period.



**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**9. Equity transactions (continued)**

On May 27, 2014, the Subscriber paid the Company the remaining \$900,000 and was issued 3,600,000 shares of unregistered common stock of the Company as full settlement of the Subscription Agreement.

**\$278,500 Convertible Promissory Note and Warrants**

On February 10, 2014, the Company entered into a financing transaction with an accredited investor for the sale of an 8% convertible promissory note (the “\$278,500 Convertible Note”) and warrants (the “Class J Warrants”) in the principal amount of \$278,500, with gross proceeds of \$250,000 to the Company after payment of a 10% original issue discount and related professional expenses.

The \$278,500 Convertible Note and Class J Warrants were issued pursuant to the terms of a purchase agreement among the Company and the holder. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on August 11, 2014. The convertible note accrued interest at the rate of 8% per annum and included a 10%, or \$25,000, original issuance discount. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 60 days was 120% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days. The \$278,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of the lower of 75% of the lowest reported sale price of the Company’s common stock for the 20 trading days immediately prior to (i) the closing date of the financing, or (ii) 75% of the lowest reported sale price for the 20 days prior the conversion date of the convertible note. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

The Class J Warrants entitle the holder to purchase, in the aggregate, 629,378 shares of the Company’s common stock. The Warrants were exercisable upon the six month anniversary of the closing date (August 10, 2014) and expire five years from the closing date. The Class J Warrants have an exercise price equal to \$0.4425. The Class J Warrants may be exercised for cash or on a cashless basis. The exercise price of the warrants is subject to adjustment for stock splits, combinations or similar events, and, in this event, the number of shares issuable upon the exercise of the warrant will

also be adjusted so that the aggregate exercise price shall be the same immediately before and immediately after the adjustment. In addition, the exercise price is also subject to a “full ratchet” anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price.

In the first quarter of 2014, the Company recorded additional interest expense of \$339,864, which was the estimated fair value of the Class J Warrants on the date of grant, February 10, 2014, calculated using the Black-Scholes pricing model using the following primary inputs of: (i) \$0.60 closing stock price on the date of grant, (ii) the expected time the warrants will be outstanding of five years, (iii) estimated discount rate of 1.48%, and (iv) expected volatility of 137% based on historical data from the Company and other companies similar in size and value to the Company.

In March 2014, the Company repaid the \$278,500 Convertible Note in full, which totaled \$337,171 with accrued interest and a prepayment penalty of \$56,195.

**\$128,500 Convertible Promissory Note**

On December 23, 2013, the Company entered into a financing transaction with an accredited investor for the sale of an 8% convertible promissory note (the “\$128,500 Convertible Note”) in the principal amount of \$128,500, with gross proceeds of \$125,000 to the Company after payment of related professional expenses.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**9. Equity transactions (continued)**

The \$128,500 Convertible Note was issued pursuant to the terms of a purchase agreement among the Company and the accredited investor. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on September 26, 2014. The convertible note accrued interest at the rate of 8% per annum. The Company had the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 30 days was 115% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days.

The \$128,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 61% of the lowest three reported sale prices of the Company's common stock for the 10 trading days immediately prior to the conversion date. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

In March 2014, the Company repaid the \$128,500 Convertible Note in full, which totaled \$158,055, with accrued interest and prepayment penalty of \$29,555.

**\$78,500 Convertible Promissory Note**

On February 18, 2014, the Company entered into a second tranche of financing with the accredited investor for the \$128,500 Convertible Note for the sale of an 8% Convertible Promissory Note (the "\$78,500 Convertible Note") under the same terms as the first tranche in the principal amount of \$78,500, with gross proceeds of \$75,000 to the Company after payment of related professional expenses.

The \$78,500 Convertible Note was issued pursuant to the terms of a purchase agreement among the Company and the accredited investor. The convertible note was an unsecured obligation of the Company and, unless earlier redeemed, matured on November 20, 2014. The convertible note accrued interest at the rate of 8% per annum. The Company had

the right to prepay the convertible note and accrued interest during the first 180 days following the date of issuance. During that time, the amount of any prepayment during the first 30 days was 115% of the outstanding amounts owed, and the amount of the prepayment increased every subsequent 30 days.

The \$78,500 Convertible Note was convertible, after the first 180 days, in whole or in part, at the option of the investor, into shares of Company common stock at a conversion price of 61% of the lowest three reported sale prices of the Company's common stock for the 10 trading days immediately prior to the conversion date. The convertible note included full ratchet anti-dilution protection for any lower priced issuances of common stock or securities convertible or exchangeable into Company common stock.

In March 2014, the Company repaid the \$78,500 Convertible Note in full, which totaled \$90,275 with accrued interest and prepayment penalty of \$11,775.

#### *Consulting Agreements*

In February 2014, the Company renewed one consulting contract and entered into three additional consulting agreements for which a portion of the fee for the services performed was paid with Company common stock. The Company issued 1,035,000 shares of common stock under these agreements in February 2014 through May 2014. The fair value of the common stock issued to the consultants, based upon the closing market price of the Company's common stock at the dates the common stock was issued, was recorded as a non-cash general and administrative expense for the periods.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**10. Preferred Stock**

The Company's Articles of Incorporation authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by the board of directors. On March 14, 2014, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for Series A Convertible Preferred Stock of the Company (the "Certificate of Designation") with the Nevada Secretary of State. The Certificate of Designation amends the Company's Articles of Incorporation to designate 6,175 shares of preferred stock, par value \$0.001 per share, as Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock has a stated value of \$1,000 per share. On March 17, 2014, in connection with the 2014 Private Placement, the Company issued 6,175 shares of Series A Convertible Preferred Stock (for a more detailed discussion regarding the 2014 Private Placement, see Note 9).

Under the Certificate of Designation, holders of Series A Convertible Preferred Stock are entitled to receive dividends equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. Such holders will participate on an equal basis per-share with holders of common stock in any distribution upon winding up, dissolution, or liquidation of the Company. Holders of Series A Convertible Preferred Stock are entitled to convert each share of Series A Convertible Preferred Stock into 2,000 shares of common stock, provided that after giving effect to such conversion, such holder, together with its affiliates, shall not beneficially own in excess of 9.99% of the number of shares of common stock outstanding (the "Beneficial Ownership Limitation"). Holders of the Series A Convertible Preferred Stock are entitled to vote on all matters affecting the holders of the common stock on an "as converted" basis, provided that such holder shall only vote such shares of Series A Convertible Preferred Stock eligible for conversion without exceeding the Beneficial Ownership Limitation.

**11. Warrants**

A summary of the warrant activity as of September 30, 2014 and December 31, 2013, and the changes during the nine months ended September 30, 2014, is presented as follows:

Outstanding

Outstanding

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| Warrant class     | as of<br>December<br>31,<br>2013 | Issued     | Exercised | Expired     | as of<br>September<br>30,<br>2014 | Exercise<br>price/share | Expiration<br>date |
|-------------------|----------------------------------|------------|-----------|-------------|-----------------------------------|-------------------------|--------------------|
| Class A Warrants  | 1,106,627                        | -          | -         | (1,106,627) | -                                 | \$ 4.00                 | Sept, 2014         |
| Class B Warrants  | 1,106,627                        | -          | -         | (1,106,627) | -                                 | \$ 8.00                 | Sept, 2014         |
| Class E Warrants  | 3,576,737                        | -          | -         | -           | 3,576,737                         | \$ 4.00                 | Apr, 2016          |
| Class F Warrants  | 300,000                          | -          | -         | -           | 300,000                           | \$ 0.35                 | Feb, 2018          |
| Class G Warrants  | 1,503,409                        | -          | -         | -           | 1,503,409                         | \$ 0.80                 | Jul, 2018          |
| Class H Warrants  | 1,988,095                        | -          | -         | -           | 1,988,095                         | \$ 0.80                 | Jul, 2018          |
| Class I Warrants  | 1,043,646                        | -          | -         | -           | 1,043,646                         | \$ 0.85                 | Sept, 2018         |
| Class J Warrants  | -                                | 629,378    | -         | -           | 629,378                           | \$ 0.44                 | Feb, 2019          |
| Series A Warrants | -                                | 25,951,421 | -         | -           | 25,951,421                        | \$ 0.50                 | Mar, 2019          |
| Series B Warrants | -                                | 15,570,852 | -         | -           | 15,570,852                        | \$ 1.50                 | Mar, 2015          |
|                   | 10,625,141                       | 42,151,651 | -         | (2,213,254) | 50,563,538                        |                         |                    |

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**12. Commitments and contingencies**

**Operating Leases**

Rent expense for the three months ended September 30, 2014 and 2013, was \$28,813 and \$22,531, respectively, and \$88,654 and \$76,508 for the nine months ended September 30, 2014 and 2013, respectively.

**Litigation**

The Company is involved in various legal matters that have arisen in the ordinary course of business. While the ultimate outcome of these matters is not presently determinable, it is the opinion of management that the resolution will not have a material adverse effect on the financial position or results of operations of the Company.

**13. Stock-based compensation**

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the "Stock Incentive Plan"). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to four years and have a ten year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. At September 30, 2014 and December 31, 2013, the Stock Incentive Plan reserved 8,500,000 shares of common stock for grant.

On September 4, 2014, the Company granted two members of the Company's Medical Advisory Board each options to purchase 75,000 shares of the Company's common stock at an exercise price of \$0.55 per share in place of an annual cash consulting fee for calendar year 2014. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of \$0.1625 resulting in compensation expense of \$24,375. Compensation cost is being recognized over the requisite service period in calendar year 2014.

On May 7, 2014, the Company granted to the active employees options to purchase 900,000 shares of common stock at an exercise price of \$0.55 per share. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of \$0.48 resulting in compensation expense of \$429,001. Compensation cost is being recognized over the requisite service period.

On February 21, 2013, the Company, by mutual agreement with all the active employees and directors of the Company, cancelled options granted to the active employees in the year ended December 31, 2011 and prior which totaled 1,113,644 shares of common stock at an average exercise price of \$2.92. In exchange for these options, the active employees and directors received new options to purchase 2,243,644 shares of common stock at an exercise price of \$0.35 per share. Using the Black-Scholes option pricing model, management has determined that the options at the grant date, net of the value of the cancelled options as of the date of cancellation, had an average fair value per share of \$0.223 resulting in total compensation of \$499,621. Compensation cost is being recognized over the requisite service period.

On February 21, 2013, the Company granted two members of the Company's Medical Advisory Board each options to purchase 50,000 shares of the Company's common stock at an exercise price of \$0.35 per share in place of an annual cash consulting fee for calendar year 2013. Using the Black-Scholes option pricing model, management has determined that the options had a fair value per share of \$0.64 resulting in compensation expense of \$64,000. Compensation cost was recognized over calendar year 2013.



**SANUWAVE HEALTH, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 30, 2014****13. Stock-based compensation (continued)**

On February 25, 2013, Joseph Chiarelli joined the Company to serve as the Chief Executive Officer and a director of the Company. Mr. Chiarelli was granted options to purchase 2,250,000 shares of the Company's common stock at an exercise price of \$0.35 per share. The options could vest and become exercisable in five installments as follows: (i) 375,000 vested at grant; (ii) 375,000 vest upon the Company completing a financing resulting in gross proceeds to the Company of no less than \$5,000,000 at a price per share of not less than \$0.35; (iii) 375,000 upon the execution by the Company of a license or distribution agreement from which the Company is entitled to receive gross proceeds of no less than \$1,000,000 and the Company has received payments of at least \$250,000; (iv) 375,000 vest upon receipt by the Company of FDA approval for the use of dermaPACE; and (v) 750,000 vest in the event the Company achieves the milestones (i), (ii), (iii) and (iv) above during the initial two year term and the term is not extended by the Company. Using the Black-Scholes option pricing model, management determined that the options had an average fair value per share of \$0.207 resulting in total compensation of \$465,000. Compensation cost will be recognized over the requisite service period. Mr. Chiarelli was terminated as Chief Executive Officer on April 15, 2014. The 1,500,000 non-vested options outstanding at that time were forfeited and compensation cost of \$217,450 that had been expensed in prior periods for these non-vested options was reversed in the three months ended June 30, 2014.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the nine months ended September 30, 2014 and 2013:

|  | 2014    |         | 2013 |
|--|---------|---------|------|
| Weighted average expected life in years  | 5.4     |         | 4.3  |
| Weighted average risk free interest rate | 1.81 %  | 0.72 %  |      |
| Weighted average volatility              | 136.1 % | 150.0 % |      |
| Forfeiture rate                          | 0.0 %   | 0.0 %   |      |
| Expected dividend yield                  | 0.0 %   | 0.0 %   |      |

The expected life of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. Since there is a limited trading history for the Company's common stock, the expected volatility is based on a combination of historical data

from companies similar in size, value and trading history for the Company's common stock. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. Management estimates pre-vesting forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest. The expected dividend yield is based on historical dividend experience, however, since inception the Company has not declared dividends.

The Company recognized as compensation cost for all outstanding stock options granted to employees, directors and advisors, \$94,032 and \$175,987 for the three months ended September 30, 2014 and 2013, respectively, and \$369,238 and \$683,382 for the nine months ended September 30, 2014 and 2013, respectively. This was offset by a reduction in compensation expense for forfeitures on non-vested options of \$60,000 and \$277,450 for the three and nine months ended September 30, 2014, respectively.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 30, 2014****13. Stock-based compensation (continued)**

A summary of option activity as of September 30, 2014 and December 31, 2013, and the changes during the three and nine months ended September 30, 2014, is presented as follows:

|                                      | Options     | Weighted<br>Average<br>Exercise<br>Price<br>per share |
|--------------------------------------|-------------|---|
| Outstanding as of December 31, 2013  | 8,366,830   | \$ 1.17   |
| Granted                              | -           | \$ -  |
| Exercised                            | (60,000 )   | \$ 0.21   |
| Cancelled                            | -           | \$ -  |
| Forfeited or expired                 | -           | \$ -  |
| Outstanding as of March 31, 2014     | 8,306,830   | \$ 1.17   |
| Granted                              | 900,000     | \$ 0.55   |
| Exercised                            | -           | \$ -  |
| Cancelled                            | -           | \$ -  |
| Forfeited or expired                 | (1,500,000) | \$ 0.35   |
| Outstanding as of June 30, 2014      | 7,706,830   | \$ 1.26   |
| Granted                              | 150,000     | \$ 0.55   |
| Exercised                            | -           | \$ -  |
| Cancelled                            | -           | \$ -  |
| Forfeited or expired                 | (600,000 )  | \$ 0.55   |
| Outstanding as of September 30, 2014 | 7,256,830   | \$ 1.31   |
| Exercisable                          | 6,279,789   | \$ 1.45   |

The range of exercise prices for options was \$0.21 to \$2.92 for options outstanding at September 30, 2014 and December 31, 2013. The aggregate intrinsic value for outstanding options was \$0 and \$1,271,540 at September 30, 2014 and December 31, 2013, respectively. The aggregate intrinsic value for all vested and exercisable options was \$0 and \$574,181 at September 30, 2014 and December 31, 2013, respectively.

The weighted average remaining contractual term for outstanding exercisable stock options was 6.67 and 6.96 years as of September 30, 2014 and December 31, 2013, respectively.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 30, 2014****13. Stock-based compensation (continued)**

A summary of the Company's nonvested options as of September 30, 2014 and December 31, 2013, and changes during the three and nine months ended September 30, 2014, is presented as follows:

|                                      | Options     | Weighted<br>Average<br>Exercise<br>Price<br>per share |
|--------------------------------------|-------------|---|
| Outstanding as of December 31, 2013  | 3,254,092   | \$ 0.35   |
| Granted                              | -           | \$ -  |
| Vested                               | (1,014,552) | \$ 0.35   |
| Cancelled                            | -           | \$ -  |
| Forfeited or expired                 | -           | \$ -  |
| Outstanding as of March 31, 2014     | 2,239,540   | \$ 0.34   |
| Granted                              | 900,000     | \$ 0.55   |
| Vested                               | (299,999 )  | \$ 0.55   |
| Cancelled                            | -           | \$ -  |
| Forfeited or expired                 | (1,500,000) | \$ 0.35   |
| Outstanding as of June 30, 2014      | 1,339,541   | \$ 0.43   |
| Granted                              | 150,000     | \$ 0.55   |
| Vested                               | (112,500 )  | \$ 0.55   |
| Cancelled                            | -           | \$ -  |
| Forfeited or expired                 | (400,000 )  | \$ 0.55   |
| Outstanding as of September 30, 2014 | 977,041     | \$ 0.38   |

**14. Earnings (loss) per share**

The Company calculates net income (loss) per share in accordance with ASC 260, *Earnings Per Share* (formerly SFAS No. 128, Earnings Per Share). Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing

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

As a result of the net loss for the three and nine months ended September 30, 2014 and 2013, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net loss per share. The anti-dilutive equity securities totaled 70,170,368 shares and 18,623,325 shares at September 30, 2014 and 2013, respectively.

## **Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this report, and together with our audited consolidated financial statements, related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as of and for the year ended December 31, 2013 included in our Annual Report on Form 10-K, filed with the SEC on March 31, 2014.*

### **Overview**

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.

We believe we have demonstrated that our patented technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe and Asia. Our lead product candidate for the global wound care market, dermaPACE, has received the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue.

We are focused on developing our Pulsed Acoustic Cellular Expression (PACE) technology to activate healing in:

wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;

orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications; stem cells, including stem cell proliferation and soft tissue regeneration;

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 cavitation effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.



## Recent Developments

The U.S. Food and Drug Administration (FDA) has granted approval of our Investigational Device Exemption (IDE) Supplement to conduct a supplemental clinical trial utilizing our lead device product for the global wound care market, the dermaPACE device, in the treatment of diabetic foot ulcers. Patient enrollment began in June 2013 and as of April 30, 2014, we had enrolled the minimum number of 90 patients in the clinical trial, which represented the number of patients for the first interim analysis by the independent Data Monitoring Committee (DMC). In September 2014, we reported that the independent Data Monitoring Committee had performed an interim analysis on the 12-week efficacy results for the first 90 patients in the clinical trial and recommended we continue enrollment of patients into the study up to the next predefined patient analysis point of 130 patients. We had continued to enroll patients while waiting on the 12-week efficacy analysis for the first 90 patients and expect to complete enrollment for the 130 patients in November 2014. We expect to suspend enrollment at that time until we receive the recommendation of the DMC on the 130 patients. We are exploring additional analysis for clinical objectives for the dermaPACE clinical trial through ongoing discussions with the FDA which could be added to the 130 subject Bayesian analysis.

The DMC will perform an analysis on the entire 130 patient population once the patients have completed the 12-week efficacy analysis period. This is expected to be completed in the first quarter of 2015. After their review of the 130 patients, the DMC may recommend: 1) stopping enrollment because the dermaPACE has met the minimum success criteria as compared to sham-control, 2) increasing enrollment to 170 patients which is the next predefined patient analysis point, or 3) stopping the trial due to poor results. Assuming positive clinical results, we will then submit the PMA to the FDA with possible FDA approval in 2016.

The double-blind, multi-center, randomized, sham-controlled, parallel group clinical trial plan incorporates the same primary efficacy endpoint of complete wound closure at 12 weeks as was utilized in the pivotal trial (discussed below). Similar to the pivotal trial, four dermaPACE procedures are administered during the first two weeks following subject enrollment. In the current trial, however, up to four additional dermaPACE procedures are delivered bi-weekly, between weeks 4 and 10 following subject enrollment, which we believe will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.

We worked closely with the FDA to amend the protocol and develop the statistical plan for the supplemental clinical study. A substantial component of this work involved using Bayesian statistical principles to define the dermaPACE treatment benefit established in our previously conducted pivotal study. Bayesian designs are supported by the FDA where there is strong prior evidence that can be incorporated into the clinical study design. By incorporating the prior positive information regarding complete wound closure after one treatment cycle into the design of the current study, substantially fewer patients are required than would otherwise be the case while still ensuring adequate statistical power. This approach saves significant time and preserves scientific rigor.

The supplemental clinical study incorporates an independent group of medical professionals who independently adjudicate wound closure of individual patients and correspond with the respective principal investigator if their decisions contradict the decisions made by the principal investigator to make a final determination on the state of closure of the wound.

Our dermaPACE device has received the European CE Mark approval to treat acute and chronic defects of the skin and subcutaneous soft tissue, such as in the treatment of pressure ulcers, diabetic foot ulcers, burns, and traumatic and surgical wounds. We are currently marketing the dermaPACE to the European Community, Canada and Asia/Pacific, utilizing distributors in select countries.

*Previous clinical work supporting our current dermaPACE clinical study*

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 July 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. The standard of care included wet-to-dry dressings, the most widely used primary dressing material in the United States, and offloading with a walking boot for ulcers located on the plantar surface of the foot.

A total of 206 patients entered the dermaPACE study at 24 sites. The patients in the study were followed for a total of 24 weeks. The study's primary endpoint, wound closure, was defined as "successful" if the skin was 100% reepithelialized at 12 weeks without drainage or dressing requirements confirmed at two consecutive study visits.

A summary of the key study findings were as follows:

Patients treated with dermaPACE showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although the rate of complete wound closure between dermaPACE and sham-control at 12 weeks in the intention-to-treat (ITT) population was not statistically significant at the 95% confidence level used throughout the study ( $p=0.363$ ). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, the FDA expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, we conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of sham-control subjects ( $p=0.047$ ); in the efficacy evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of sham-control subjects ( $p=0.018$ ). Subjects treated with dermaPACE achieved a significant increase in the rate of complete and/or  $\geq 90\%$  wound closure. We analyzed a clinically relevant  $\geq 90\%$  wound closure endpoint that demonstrated statistical significance ( $p=0.0161$ ) in favor of dermaPACE subjects (51/107, 48%) compared to patients randomized to receive sham-control (31/99, 31%).

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

Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20.0% in the sham-control group.

Importantly, there were no meaningful statistical differences in the adverse event rates between the dermaPACE treated patients and the sham-control group. There were no issues regarding the tolerability of the treatment which suggests that a second course of treatment, if needed, is a clinically viable option.

We filed with the FDA the clinical module of the dermaPACE PMA application in June 2011. 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. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

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.

## Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2014, we had cash and cash equivalents totaling \$4,687,222. Management believes that these funds will support our operations into the third quarter of 2015. We expect to complete the dermaPACE clinical trial and, assuming positive clinical results at the 130 patient mark, submit the PMA to the FDA in the third quarter of 2015 for possible FDA approval in 2016.

Management expects the cash used in operations for the Company in 2014 will be approximately \$550,000 to \$650,000 per month through December 2014 as substantial resources are devoted to the patient enrollment and follow-up phases of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers and will be approximately \$450,000 to \$550,000 per month thereafter in 2015.

We do not currently generate significant recurring revenue and will require additional capital in the second half of 2015 to complete the FDA approval process for the dermaPACE, assuming positive clinical study results, and repay the Notes Payable, Related Parties. Should we not be successful in obtaining FDA approval, we will need to explore strategic alternatives and obtain additional financing to sustain operations. We may raise 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 by selling all or a portion of the Company's assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us.

Since our inception, we have incurred losses from operations each year. As of September 30, 2014, we had an accumulated deficit of \$87,960,552. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses will continue over the next several years as we continue to fund the dermaPACE clinical trial and the FDA approval process.

We cannot reasonably estimate the nature, timing and costs of the efforts necessary to complete the development and approval of, or the period in which material net cash flows are expected to be generated from, any of our products, due to the numerous risks and uncertainties associated with developing products, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of successful marketing, sales and distribution;
- the cost and timing associated with establishing reimbursement for our products;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior.

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth under the section entitled "Risk Factors – Risks Related to Our Business" in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014.

### **Critical Accounting Policies and Estimates**

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

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

On an ongoing basis, we evaluate our estimates and judgments, including those related to the recording of the allowances for doubtful accounts, estimated reserves for inventory, estimated useful life of property and equipment, the determination of the valuation allowance for deferred taxes, the estimated fair value of stock-based compensation, and the estimated fair value of intangible assets. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements filed with our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, intangible assets, stock-based compensation and income taxes are significant and; therefore, they are important to aid you in fully understanding and evaluating our reported financial results.

### ***Revenue Recognition***

Sales of medical devices, including related applicators and applicator kits, are recognized when shipped to the customer. Shipments under agreements with distributors are invoiced at a fixed price, are not subject to return, and payment for these shipments is not contingent on sales by the distributor. We recognize revenue on shipments to distributors in the same manner as with other customers. We recognize fees from services performed when the service is performed.

### ***Research and Development Costs***

We expense costs associated with research and development activities as incurred. We evaluate payments made to suppliers and other vendors and determine the appropriate accounting treatment based on the nature of the services provided, the contractual terms, and the timing of the obligation. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs.

### ***Inventory Valuation***

We value our inventory at the lower of our actual cost or the current estimated market value. We regularly review existing inventory quantities and expiration dates of existing inventory to evaluate a provision for excess, expired, obsolete and scrapped inventory based primarily on our historical usage and anticipated future usage. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated change in demand or technological developments could have an impact on the value of our inventory and our reported operating results.

Inventory is carried at the lower of cost or market, which is valued using the first in, first out (FIFO) method, and consists primarily of devices and the component material for assembly of finished products, less reserves for obsolescence.

### ***Intangible Assets***

Intangible assets subject to amortization consist of patents which are recorded at cost. Patents are amortized on a straight-line basis over the average life of 11.4 years. We regularly review intangible assets to determine if facts and circumstances indicate that the useful life is shorter than we originally estimated or that the carrying amount of the assets may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the intangible assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If recognition of an impairment charge is necessary, it is measured as the amount by which the carrying amount of the intangible asset exceeds the fair value of the intangible asset.

### ***Stock-based Compensation***

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

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

### ***Income Taxes***

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109, Accounting for Income Taxes). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets, including loss carryforwards, when it is more likely than not that some portion or all of a deferred tax asset will not be realized.



We account for uncertain tax positions in accordance with the related provisions of ASC 740, *Income Taxes* (formerly FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48)). ASC 740 specifies the way public companies are to account for uncertainties in income tax reporting, and prescribes a methodology for recognizing, reversing, and measuring the tax benefits of a tax position taken, or expected to be taken, in a tax return. ASC 740 requires the evaluation of tax positions taken or expected to be taken in the course of preparing our tax returns to determine whether the tax positions would “more-likely-than-not” be sustained if challenged by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax benefit or expense in the current year.

### **Results of Operations for the Three Months ended September 30, 2014 and 2013 (Unaudited)**

#### *Revenue and Cost of Revenue*

Revenue for the three months ended September 30, 2014 was \$227,492, compared to \$148,421 for the same period in 2013, an increase of \$79,071, or 53%. Revenue resulted primarily from sales in Europe, Asia and Asia/Pacific of our dermaPACE and orthoPACE devices and related applicators. The increase in revenue for 2014 was due to higher sales of orthoPACE devices in 2014 in Asia/Pacific, as compared to the prior year, as well as higher sales in refurbished applicators in Europe.

Cost of revenue for the three months ended September 30, 2014 was \$68,077, compared to \$29,467 for the same period in 2013. Gross profit as a percentage of revenue was 70% for the three months ended September 30, 2014, compared to 80% for the same period in 2013. The decrease in gross profit as a percentage of revenue in 2014 was due to a greater portion of revenue being from the sale of devices in 2014, which have a lower margin than applicators.

#### *Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2014 were \$708,304, compared to \$775,717 for the same period in 2013, a decrease of \$67,413, or 9%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs. Research and development expenses decreased in 2014 as a result of higher start-up costs for third parties used in the dermaPACE clinical study in 2013 at the start of the more costly enrollment phase in June 2013.

*General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2014 were \$780,115, as compared to \$1,151,709 for the same period in 2013, a decrease of \$371,594, or 32%. The decrease in general and administrative expenses is primarily due to reduced stock-based compensation expense for 2014 due to the forfeiture of non-vested stock options by terminated employees and reduced financial related consulting expenses with the completion of the private placement in March 2014.

*Other Income (Expense)*

Other income (expense) was an expense of \$83,385 for the three months ended September 30, 2014, as compared to an expense of \$2,546,775 for the same period in 2013, a decrease in other expense of \$2,463,390. The decrease in other expense for 2014 was due to a non-cash loss in 2013 of \$964,813 from the embedded conversion feature of the Senior Secured Notes which were converted to equity during the quarter, a non-cash loss on extinguishment of the Senior Secured Notes of \$1,073,572 for the fair value of the warrants issued to the note holders, and \$421,060 in non-cash amortization expense of the debt discount on the embedded conversion feature of the Senior Secured Notes and interest expense on the Senior Secured Notes.

*Provision for Income Taxes*

At September 30, 2014, we had federal net operating loss carryforwards of \$59,355,168 through the year ended December 31, 2013 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

*Net Loss*

Net loss for the three months ended September 30, 2014 was \$1,492,905, or (\$0.03) per basic and diluted share, compared to a net loss of \$4,436,790, or (\$0.14) per basic and diluted share, for the same period in 2013, a decrease in the net loss of \$2,943,885, or 66%. The decrease in the net loss for 2014 was primarily a result of the non-cash other expenses which totaled \$2,459,445 in 2013 for the embedded conversion feature of the Senior Secured Notes, the loss on extinguishment of the Senior Secured Notes which were converted to equity in the third quarter of 2013, and the accrued interest expense on the Senior Secured Notes.

We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device clinical trial for the treatment of diabetic foot ulcers and the related FDA approval process, assuming positive clinical results.

**Results of Operations for the Nine Months ended September 30, 2014 and 2013 (Unaudited)**

*Revenue and Cost of Revenue*

Revenue for the nine months ended September 30, 2014 was \$610,705, compared to \$510,272 for the same period in 2013, an increase of \$100,433, or 20%. Revenue resulted primarily from sales in Europe, Asia and Asia/Pacific of our dermaPACE and orthoPACE devices and related applicators. The increase in revenue for 2014 was due to higher sales of orthoPACE devices in 2014 in Asia/Pacific, as compared to the prior year, as well as higher sales in refurbished applicators in Europe.

Cost of revenue for the nine months ended September 30, 2014 was \$149,813, compared to \$109,061 for the same period in 2013. Gross profit as a percentage of revenue was 75% for the nine months ended September 30, 2014, compared to 79% for the same period in 2013. The decrease in gross profit as a percentage of revenue in 2014 was due to a greater portion of revenue being from the sale of devices in 2014, which have a lower margin than applicators.

*Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2014 were \$2,486,801, compared to \$1,744,935 for the same period in 2013, an increase of \$741,866, or 43%. Research and development costs include payments to third parties that specifically relate to our products in clinical development, such as payments to contract research organizations, clinical investigators, clinical monitors, clinical related consultants and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the regulatory affairs, clinical affairs, quality assurance, and research and development departments are classified as research and development costs. Research and development expenses increased in 2014 as a result of the dermaPACE clinical study starting the more costly enrollment phase in June 2013.

*General and Administrative Expenses*

General and administrative expenses for the nine months ended September 30, 2014 were \$2,774,828, as compared to \$3,160,749 for the same period in 2013, a decrease of \$385,921, or 12%. The decrease in general and administrative expenses is primarily due to reduced stock-based compensation expense for 2014 due to the forfeiture of non-vested stock options by terminated employees and reduced financial related consulting expenses with the completion of the private placement in March 2014.

*Other Income (Expense)*

Other income (expense) was an expense of \$706,393 for the nine months ended September 30, 2014, as compared to an expense of \$5,875,078 for the same period in 2013, a decrease in other expense of \$5,168,685. The other expense in 2014 included a non-cash loss of \$339,864 charged to interest expense for the fair value of the warrants issued concurrently with a convertible promissory note in February 2014. The other expense in 2013 included a non-cash loss of \$2,373,813 for the embedded conversion feature of the Senior Secured Notes, the loss on extinguishment of the Senior Secured Notes of \$1,073,572 which were converted to equity in the third quarter of 2013, and \$2,178,390 for the accrued interest expense on the Senior Secured Notes, including amortization of the debt discount. The Senior Secured Notes were converted to equity during the third quarter of 2013.

*Provision for Income Taxes*

At September 30, 2014, we had federal net operating loss carryforwards of \$59,355,168 through the year ended December 31, 2013 that will begin to expire in 2025. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. In connection with possible future equity offerings, we may realize a “more than 50% change in ownership” which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss carryforwards for federal income tax purposes.

*Net Loss*

Net loss for the nine months ended September 30, 2014 was \$5,750,509, or (\$0.12) per basic and diluted share, compared to a net loss of \$10,624,454, or (\$0.43) per basic and diluted share, for the same period in 2013, a decrease in the net loss of \$4,873,945, or 46%. The decrease in the net loss for 2014 was primarily a result of the non-cash other expenses which totaled \$5,625,775 in 2013 for the embedded conversion feature of the Senior Secured Notes, the loss on extinguishment of the Senior Secured Notes which were converted to equity in the third quarter of 2013, and the accrued interest expense on the Senior Secured Notes. These other expenses were offset by increased research and development expenses in 2014 for the dermaPACE clinical study.

We anticipate that our operating losses will continue over the next several years as we continue to fund our dermaPACE device clinical trial for the treatment of diabetic foot ulcers and the related FDA approval process, assuming positive clinical results.

## **Liquidity and Capital Resources**

Since inception in 2005, our operations have primarily been funded from the sale of capital stock and convertible debt securities. At September 30, 2014, we had cash and cash equivalents totaling \$4,687,222 and negative working capital of \$1,131,755. For the nine months ended September 30, 2014 and 2013, the net cash used by operating activities was \$5,542,192 and \$3,374,894, respectively. Since inception, we have experienced recurring losses from operations and had an accumulated deficit of \$87,960,552 at September 30, 2014.

We do not currently generate significant recurring revenue and will require additional capital in the second half of 2015 to obtain FDA approval for the dermaPACE in 2016, assuming positive clinical study results. Although no assurances can be given, management believes that existing capital resources should enable us to fund operations into the third quarter of 2015. Our unsecured Notes Payable, Related Parties, which total \$5,372,743 at September 30, 2014, are due on August 1, 2015.

The continuation of our business is dependent upon raising additional capital in the second half of 2015 to fund operations and repay the Notes Payable, Related Parties or amend the note terms to extend the notes and/or consider other non-cash repayment options. Management's plans are to obtain additional capital in 2015 through investments by strategic partners in specific clinical indications or market opportunities, which may include strategic partnerships or other licensing arrangements.

In addition, we may raise capital through the conversion of outstanding warrants, the issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt, or by selling all or a portion of our assets (or some combination of the foregoing). If these efforts are unsuccessful, we may be forced to seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions as discussed above should provide the necessary funding for us to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

On May 27, 2014, we received \$900,000 as the final payment on the Subscription Agreement with a related party.

On March 17, 2014, we completed a private placement of securities for an aggregate total purchase price of \$9,280,000 (previously defined as the “2014 Private Placement”). In addition, we raised \$815,000 through the issuance of unsecured 18% Convertible Promissory Notes in the first quarter of 2014, which by their terms, converted into equity at the same terms as the 2014 Private Placement on March 17, 2014.

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

For the nine months ended September 30, 2014 and 2013, net cash used by operating activities was \$5,542,192 and \$3,374,894, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The increase in the use of cash for operating activities for the nine months ended September 30, 2014, as compared to the same period for 2013, of \$2,167,298, or 64%, was primarily due to the increased research and development expenses in 2014, as compared to 2013, of \$741,866 for expenses associated with the dermaPACE clinical trial including the costs for our clinical research organization, clinical monitors and the clinical site costs related to the patients enrolled during the period as a result of the clinical study starting the more costly enrollment phase in June 2013 and the reduction of accounts payable and accrued expenses in 2014 of \$1,036,708. Net cash provided by financing activities for the nine months ended September 30, 2014 and 2013 was \$10,071,149 and \$3,636,703, respectively, which in 2014 primarily consisted of the net proceeds from the 2014 Private Placement of \$8,562,500, the proceeds from sale of capital stock per the Subscription Agreement with a related party of \$900,000, and the proceeds from the 18% Convertible Promissory notes of \$815,000. In 2013, net cash provided by financing activities primarily consisted of the net proceeds from the subscriptions payable for Senior Secured Notes of \$1,570,000 and net proceeds from the July 2013 public offering of \$1,517,450. Cash and cash equivalents increased by \$4,504,907 and \$263,505 for the nine months ended September 30, 2014 and 2013, respectively.

## **Segment and Geographic Information**

We have determined that we are principally engaged in one operating segment. Our products are primarily used for the repair and regeneration of tissue, musculoskeletal and vascular structures in wound healing and orthopedic conditions. Our revenues are generated from sales in Europe, Canada, Asia and Asia/Pacific.

## **Contractual Obligations**

Our major outstanding contractual obligations relate to our operating leases for our facility, purchase and supplier obligations for product component materials and equipment, and our notes payable. We have disclosed these obligations in our most recent Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the SEC on March 31, 2014.



### **Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

### **Effects of Inflation**

Because our assets are, to an extent, liquid in nature, they are not significantly affected by inflation. However, the rate of inflation affects such expenses as employee compensation, office space leasing costs and research and development charges, which may not be readily recoverable during the period of time that we are bringing the product candidates to market. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations.

### **Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

### **Item 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act are accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation under the supervision and with the participation of our management, including our Co-Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2014. Based on this evaluation, the Co-Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2014.

### **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 6. EXHIBITS

| <u>Exhibit<br/>No.</u> | <u>Description</u>   |
|------------------------|--|
| 2.1                    | Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009). |
| 3.1                    | Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).   |
| 3.2                    | Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).   |
| 3.3                    | Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).   |
| 3.4                    | Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).  |
| 3.5                    | Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).              |
| 31.1*                  | Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer.   |
| 31.2*                  | Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.   |
| 32.1*                  | Section 1350 Certification of the Principal Executive Officer.   |
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101.INS\*\*XBRL Instance.

101.SCH\*\*XBRL Taxonomy Extension Schema.

101.CAL\*\*XBRL Taxonomy Extension Calculation.

101.DEF\*\* XBRL Taxonomy Extension Definition.

101.LAB\*\* XBRL Taxonomy Extension Labels.

101.PRE\*\* XBRL Taxonomy Extension Presentation.

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\* Filed herewith.

\*\* XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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## SIGNATURES

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

Dated: November 12, 2014

SANUWAVE HEALTH, INC.

By: /s/ Kevin A. Richardson, II

Kevin A. Richardson, II

Co-Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

| Signatures                             | Capacity                                     | Date              |
|--|--|-------------------|
|  | Co-Chief Executive Officer and               |                   |
| By: <u>/s/ Kevin A. Richardson, II</u> | Chairman of the Board of Directors           |                   |
| Name: Kevin A. Richardson, II          | (principal executive officer)                | November 12, 2014 |
| By: <u>/s/ Barry J. Jenkins</u>        | Chief Financial Officer                      |                   |
| Name: Barry J. Jenkins                 | (principal financial and accounting officer) | November 12, 2014 |
| By: <u>/s/ John F. Nemelka</u>         | Director                                     |                   |
| Name: John F. Nemelka                  |  | November 12, 2014 |

By: /s/ Alan L. Rubino

Director

November 12, 2014

Name: Alan L. Rubino

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