SANUWAVE Health, Inc.
Form 424B3
November 13, 2013

**Filed pursuant to Rule 424(b)(3) and Rule 424(c)**

**File No. 333-187625**

**Prospectus Supplement No. 3**
**(To Prospectus dated July 15, 2013)**

**SANUWAVE HEALTH, INC.**

**Up to 10,909,091 Units Consisting of**

**10,909,091 Shares of Common Stock and**

**Warrants to Purchase 5,454,545 Shares of Common Stock**

_____

This prospectus supplement supplements the prospectus dated July 15, 2013 (the "Prospectus"), related to the offering of up to 10,909,091 Units at a purchase price of $0.55 per Unit, with each Unit consisting of one share of our common stock and a warrant to purchase up to an additional 1/2 share of our common stock at an exercise price per share of $0.80. The securities are being offered on a "best efforts" basis, and we are not required to sell any specific dollar amount or number of Units. This prospectus supplement should be read in conjunction with the Prospectus.

This prospectus supplement contains the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013 filed by the Company with the Securities and Exchange Commission on November 12, 2013 (the "10-Q"). The 10-Q, as filed (but without the exhibits filed with the 10-Q), is set forth below. This prospectus supplement is not complete without, and may not be delivered or used except in connection with, the Prospectus. This prospectus supplement is qualified by reference to the Prospectus except to the extent that the information in this prospectus supplement updates and supersedes the information contained in the Prospectus.

_____

**Investing in our common stock involves a high degree of risk.**
**See Risk Factors beginning on page 6 of the Prospectus.**

_____

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

_____

The date of this prospectus supplement is November 13, 2013

**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, 2013**

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

**For the transition period from _____ to**

**Commission File Number 000-52985**

**SANUWAVE Health, Inc.**

(Exact name of registrant as specified in its charter)

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

(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 (Do not check if a smaller reporting company) | 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 8, 2013, there were issued and outstanding 37,561,515 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, 2012, filed on March 26, 2013 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, 2012, filed on March 26, 2013.

*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 30, 2013 | December 31, 2012 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $333,830 | $70,325 |
| Accounts receivable - trade, net of allowance for doubtful accounts of $44,475 in 2013 and $44,124 in 2012 | 65,920 | 87,826 |
| Inventory | 243,758 | 292,665 |
| Prepaid expenses | 88,760 | 128,495 |
| TOTAL CURRENT ASSETS | 732,268 | 579,311 |
| PROPERTY AND EQUIPMENT, at cost, less accumulated depreciation (Note 4) | 18,006 | 32,842 |
| OTHER ASSETS | 11,384 | 11,358 |
| INTANGIBLE ASSETS, at cost, less accumulated amortization (Note 5) | 996,958 | 1,227,025 |
| TOTAL ASSETS | $1,758,616 | $1,850,536 |
| LIABILITIES | | |
| CURRENT LIABILITIES | | |
| Accounts payable | $390,040 | $555,898 |
| Accrued expenses (Note 6) | 833,641 | 721,916 |
| Accrued employee compensation | 428,233 | 534,659 |
| Promissory notes (Note 7) | 36,450 | - |
| Subscription payable for senior secured convertible promissory notes (Note 8) | - | 438,516 |
| Interest payable, related parties (Note 9) | 81,864 | 81,864 |
| Capital lease payable, current portion (Note 13) | 5,220 | 4,933 |
| Liabilities related to discontinued operations | 655,061 | 655,061 |
| TOTAL CURRENT LIABILITIES | 2,430,509 | 2,992,847 |
| NON-CURRENT LIABILITIES | | |
| Notes payable, related parties (Note 9) | 5,372,743 | 5,372,743 |

| | | |
|---|---|---|
| Capital lease payable, non-current portion (Note 13) | - | 3,951 |
| TOTAL NON-CURRENT LIABILITIES | 5,372,743 | 5,376,694 |
| TOTAL LIABILITIES | 7,803,252 | 8,369,541 |
| | | |
| COMMITMENTS AND CONTINGENCIES (Note 13) | | |
| | | |
| STOCKHOLDERS' DEFICIT | | |
| PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding | - | - |
| | | |
| COMMON STOCK, par value $0.001, 150,000,000 shares authorized; 37,196,536 and 21,007,536 issued and outstanding in 2013 and 2012, respectively | 37,197 | 21,008 |
| | | |
| ADDITIONAL PAID-IN CAPITAL | 75,445,631 | 64,357,193 |
| | | |
| ACCUMULATED OTHER COMPREHENSIVE INCOME | 7,312 | 13,116 |
| | | |
| ACCUMULATED DEFICIT | (81,534,776) | (70,910,322) |
| TOTAL STOCKHOLDERS' DEFICIT | (6,044,636 ) | (6,519,005 ) |
| TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT | $1,758,616 | $1,850,536 |

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

| | Three Months Ended September 30, 2013 | Three Months Ended September 30, 2012 | Nine Months Ended September 30, 2013 | Nine Months Ended September 30, 2012 |
|---|---|---|---|---|
| REVENUE | $148,421 | $178,256 | $510,272 | $627,153 |
| COST OF REVENUE | 29,467 | 43,965 | 109,061 | 197,898 |
| GROSS PROFIT | 118,954 | 134,291 | 401,211 | 429,255 |
| OPERATING EXPENSES | | | | |
| Research and development | 775,717 | 440,193 | 1,744,935 | 1,391,634 |
| General and administrative | 1,151,709 | 977,859 | 3,160,749 | 3,252,127 |
| Depreciation | 4,854 | 4,973 | 14,836 | 15,313 |
| Amortization | 76,689 | 76,689 | 230,067 | 230,067 |
| TOTAL OPERATING EXPENSES | 2,008,969 | 1,499,714 | 5,150,587 | 4,889,141 |
| OPERATING LOSS | (1,890,015) | (1,365,423) | (4,749,376) | (4,459,886) |
| OTHER INCOME (EXPENSE) | | | | |
| Loss on embedded conversion feature of Senior Secured Notes (Note 8) | (964,813) | - | (2,373,813) | - |
| Loss on extinguishment of Senior Secured Notes (Note 8) | (1,073,572) | - | (1,073,572) | - |
| Accretion of interest and interest expense on Senior Secured Notes (Note 8) | (421,060) | - | (2,178,390) | - |
| Interest expense, net | (88,772) | (81,894) | (256,472) | (241,196) |
| Gain on sale of fixed assets | - | - | 7,500 | - |
| Gain (loss) on foreign currency exchange | 1,442 | 46 | (331) | (6,130) |
| TOTAL OTHER INCOME (EXPENSE) | (2,546,775) | (81,848) | (5,875,078) | (247,326) |
| LOSS BEFORE INCOME TAXES | (4,436,790) | (1,447,271) | (10,624,454) | (4,707,212) |
| INCOME TAX EXPENSE | - | - | - | - |

| | | | | |
|---|---|---|---|---|
| NET LOSS | (4,436,790 ) | (1,447,271 ) | (10,624,454) | (4,707,212 ) |
| | | | | |
| OTHER COMPREHENSIVE LOSS | | | | |
| Foreign currency translation adjustments | (1,829 ) | 4,623 | (5,804 ) | 3,589 |
| TOTAL COMPREHENSIVE LOSS | $(4,438,619 ) | $(1,442,648 ) | $(10,630,258) | $(4,703,623 ) |
| | | | | |
| LOSS PER SHARE: | | | | |
| Net loss - basic | $(0.14 ) | $(0.07 ) | $(0.43 ) | $(0.23 ) |
| Net loss - diluted | $(0.14 ) | $(0.07 ) | $(0.43 ) | $(0.23 ) |
| | | | | |
| Weighted average shares outstanding - basic | 31,874,479 | 20,907,536 | 24,969,972 | 20,907,536 |
| Weighted average shares outstanding - diluted | 31,874,479 | 20,907,536 | 24,969,972 | 20,907,536 |

The accompanying notes to condensed consolidated financial

statements are an integral part of these statements.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

| | Nine Months Ended September 30, 2013 | Nine Months Ended September 30, 2012 |
|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | $(10,624,454) | $(4,707,212) |
| Adjustments to reconcile net loss to net cash used by operating activities | | |
| Amortization | 230,067 | 230,067 |
| Depreciation | 14,836 | 15,313 |
| Change in allowance for doubtful accounts | 352 | (27,539) |
| Stock-based compensation - employees, directors and advisors | 683,382 | 719,732 |
| Stock issued for consulting services | 751,587 | - |
| Loss on embedded conversion feature of Senior Secured Notes | 2,373,813 | - |
| Accretion of interest and accured 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 | 21,554 | 30,817 |
| Inventory | 48,907 | 101,386 |
| Prepaid expenses | 39,735 | (40,157) |
| Due from Pulse Veterinary Technologies, LLC | - | 27,837 |
| Other | (26) | 1 |
| Changes in liabilities - increase/(decrease) | | |
| Accounts payable | (165,858) | (354,299) |
| Accrued employee compensation | (106,426) | 474,750 |
| Accrued expenses | 111,725 | (16,995) |
| Promissory notes - accrued interest | 1,450 | - |
| NET CASH USED BY OPERATING ACTIVITIES | (3,374,894) | (3,546,299) |
| | | |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Sale of property and equipment | 7,500 | - |
| Purchase of property and equipment | - | (2,011) |
| NET CASH PROVIDED (USED) BY INVESTING ACTIVITIES | 7,500 | (2,011) |

| | | |
|---|---|---|
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| 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 | - |
| Proceeds from sale of capital stock - subscription agreement with related party | 75,000 | - |
| Proceeds from employee stock option exercise | 37,917 | - |
| Payments of principal on promissory notes | (325,000) | - |
| Payments of principal on capital lease | (3,664) | (3,399) |
| NET CASH PROVIDED (USED) BY FINANCING ACTIVITIES | 3,636,703 | (3,399) |
| | | |
| EFFECT OF EXCHANGE RATES ON CASH | (5,804) | 3,589 |
| | | |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 263,505 | (3,548,120) |
| | | |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 70,325 | 3,909,383 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $333,830 | $361,263 |
| | | |
| SUPPLEMENTAL INFORMATION | | |
| Cash paid for interest, related parties | $242,904 | $242,903 |
| Cash paid for capital lease interest | $411 | $676 |

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, 2013**

## 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 solicit 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 2015 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. The Company is not currently marketing any commercial products in the United States. Revenue is from sales of the European Conformity Marking ("CE Mark") devices and accessories in Europe, Canada 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. Going concern

As of September 30, 2013, the Company had cash and cash equivalents of $333,830 and negative working capital of $1,698,241. For the nine months ended September 30, 2013 and 2012, the net cash used by operating activities was $3,374,894 and $3,546,299, respectively. The Company incurred a net loss of $10,624,454 for the nine months ended September 30, 2013 and a net loss of $6,401,494 for the year ended December 31, 2012. Since inception, the Company has experienced recurring losses from operations and had an accumulated deficit of $81,534,776 at September 30, 2013. As a result, there is substantial doubt as to the Company's ability to continue as a going concern.

On September 30, 2013, the Company, in conjunction with an offering of securities (the "Private Offering") of the Company pursuant to an exemption from registration under the Securities Act of 1933, as amended (the "Act"), issued 675,000 units (as described below) to certain "accredited investors," as that term is defined in the Securities and Exchange Commission's (the "SEC") Rule 501 under the Act, for an aggregate total purchase price of $405,000. In addition, in October 2013, after the end of the third quarter of 2013, in conjunction with the Private Offering, the Company issued an additional 201,979 units for an aggregate total purchase price of $121,187. Each unit was sold at a purchase price of $0.60 per unit with each "unit" consisting of; (i) one share of common stock and (ii) a five-year warrant to purchase one share of common stock at an exercise price of $0.85.

On July 25, 2013, the Company consummated a public offering (the "Public Offering") of an aggregate of 3,006,818 units, with each unit consisting of one share of Company common stock and a warrant to purchase one-half share of a common stock, resulting in warrants to purchase up to 1,503,409 shares of common stock. The price per unit was $0.55 resulting in gross proceeds of $1,653,750. The Company received net proceeds, after payment of the placement agent's fees, of $1,517,450. The units separated immediately and the common stock and warrants were issued separately. The warrants have an exercise price of $0.80 per share and are exercisable during the five-year period beginning on the date of issuance.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**2. Going concern (continued)**

The continuation of the Company's business is dependent upon raising additional capital in the fourth quarter of 2013. Management's plans are to obtain additional capital in the fourth quarter of 2013 through the issuance of common stock and/or other debt or equity securities and the Company has engaged financial advisors to assist with this process. The Company's cash and cash equivalents at September 30, 2013, combined with the proceeds from the Private Offering in October 2013, and/or amounts received on the Company's subscription agreement with an affiliated shareholder (see Note 13) is expected to support the Company's operations through the completion, in the fourth quarter of 2013, of an anticipated capital raise as discussed above. Management expects the Company's monthly use of cash in the fourth quarter of 2013 and the first half of 2014 will be approximately $575,000 to $625,000 as the Company devotes substantial resources to the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers. The Company estimates the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

The Company 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 (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. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" in this Form 10-Q.

**3. 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, 2013 and for the three and nine months ended September 30, 2013 and 2012 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, 2013 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2013.

The condensed consolidated balance sheet at December 31, 2012 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.

***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, 2012, filed with the SEC on March 26, 2013.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

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

Fair Value Measurements

The carrying amounts reported in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable - trade, accounts payable, accrued expenses and promissory notes approximate fair value due to the short-term nature of these instruments.

The Company has adopted ASC 820-10, *Fair Value Measurements* (formerly SFAS No. 157), which defines fair value, establishes a framework for measuring fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820-10 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 - Unobservable inputs that are not corroborated by market data, therefore requiring the Company to develop its own assumptions.

The following table sets forth a summary of changes in the fair value of the derivative liability for the three and nine months ended September 30, 2013:

Embedded

| | Conversion Feature of Senior Secured Notes |
|---|---|
| Balance at December 31, 2012 | $- |
| New issuances | 4,908,000 |
| Change in fair value | 829,000 |
| Balance at March 31, 2013 | 5,737,000 |
| Change in fair value | (2,328,000) |
| Balance at June 30, 2013 | 3,409,000 |
| Conversion to equity | (3,409,000) |
| Balance at September 30, 2013 | $- |

The Company accounts for derivative instruments under ASC 815, *Accounting for Derivative Instruments and Hedging Activities*, as amended and interpreted. ASC 815 requires that the Company recognize all derivatives on the balance sheet at fair value. On March 8, 2013, the Company completed an offering and issued Senior Secured Notes that contained an embedded conversion feature which was accounted for as a derivative liability. In recording this derivative liability, $2,000,000 was recorded as a debt discount and the remaining value, along with the gains (losses) resulting from the changes in the fair value of the derivative instruments, was recorded in the “gain (loss) on embedded conversion feature of Senior Secured Notes” in the accompanying condensed consolidated statements of comprehensive loss. The fair value of the embedded conversion feature was determined based on a lattice solution, binomial approach pricing model, and includes the use of unobservable inputs such as the expected term, anticipated volatility and risk-free interest rate.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

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

The Company's notes payable, related parties, consist of $5,372,743 of principal at September 30, 2013 and December 31, 2012. Interest accrues on the notes at a rate of 6% per annum. The fair value was determined using estimated future cash flows discounted at current rates, which is a Level 3 measurement. The estimated fair value of the Company's notes payable, related parties was $4,775,110 and $4,545,620 at September 30, 2013 and December 31, 2012, respectively.

***Recently Issued Accounting Standards***

New accounting pronouncements are issued by the Financial Accounting 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 February 2013, the FASB issued Accounting Standards Update ("ASU") No. 2013-02, which amends the guidance in Accounting Standards Codification ("ASC") 220 on Comprehensive Income. Under the revised guidance, companies are required to provide information about the amounts reclassified out of accumulated other comprehensive income ("AOCI") by component. In addition, companies are required to present, either on the face of the statement where net income (loss) is presented or in the notes, the effects on the line items of net income (loss) of significant amounts reclassified out of AOCI but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income (loss) in its entirety in the same reporting period. This amended guidance is to be applied prospectively and is effective for reporting periods (interim and annual) beginning after December 15, 2012 for public companies, with early adoption permitted. The Company adopted the revised guidance January 1, 2013, and reported significant items reclassified out of AOCI in the notes to the condensed consolidated financial statements (see Note 16).

**4. Property and equipment**

Property and equipment consists of the following:

| | September 30, 2013 | December 31, 2012 |
|---|---|---|
| Machines and equipment | $233,793 | $233,793 |
| Office and computer equipment | 179,349 | 179,349 |
| Software | 41,872 | 41,872 |
| Furniture and fixtures | 25,679 | 25,679 |
| Vehicles | - | 22,531 |
| Other assets | 2,446 | 2,446 |
| Total | 483,139 | 505,670 |
| Accumulated depreciation | (465,133) | (472,828) |
| Net property and equipment | $18,006 | $32,842 |

The aggregate depreciation related to property and equipment charged to operations was $4,854 and $4,973 for the three months ended September 30, 2013 and 2012, respectively, and $14,836 and $15,313 for the nine months ended September 30, 2013 and 2012, respectively.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

## 5. Intangible assets

Intangible assets consist of the following:

| | September 30, 2013 | December 31, 2012 |
|---|---|---|
| Patents, at cost | $3,502,135 | $3,502,135 |
| Less accumulated amortization | (2,505,177) | (2,275,110) |
| Net intangible assets | $996,958 | $1,227,025 |

The aggregate amortization charged to operations was $76,689 and $76,689 for the three months ended September 30, 2013 and 2012, respectively, and $230,067 and $230,067 for the nine months ended September 30, 2013 and 2012, respectively.

## 6. Accrued expenses

Accrued expenses consist of the following:

| | September 30, 2013 | December 31, 2012 |
|---|---|---|
| Accrued executive severance | $400,000 | $542,269 |
| Accrued clinical expenses | 206,489 | - |
| Accrued audit and tax preparation | 73,700 | 102,600 |

| | | |
|---|---|---|
| Accrued legal professional fees | 44,500 | 23,519 |
| Accrued board of director fees | 25,333 | - |
| Accrued other | 83,619 | 53,528 |
| | $833,641 | $721,916 |

**7. Promissory notes**

The Company issued short-term, unsecured promissory notes, in the aggregate principal amount of $360,000, between May 14, 2013 and July 9, 2013, to certain existing shareholders. The promissory notes accrue interest at a rate of 18% per annum and, together with all accrued and unpaid interest, are due and payable 179 days from their individual issuance date. In the event that the promissory notes are not paid in full within three business days of their respective maturity dates, then, from and after such maturity date and until payment in full, interest will accrue on the outstanding principal balance at the rate of 25% per annum.

Joseph Chiarelli, the Company's Chief Executive Officer, purchased promissory notes in the offering in the principal amount of $35,000. David N. Nemelka, the brother of John F. Nemelka, who is a member of the Company's board of directors, purchased promissory notes in the offering in the principal amount of $100,000.

On August 1, 2013, at the request of the promissory note holders, the Company repaid $325,000 of the original principal value of the notes in full, along with accrued interest of $10,664. At September 30, 2013, there was one promissory note outstanding for $36,450, including accrued interest, payable to Joseph Chiarelli.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

## 8. 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 – the market price at the time the subscription agreement was written. 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 market price at the time the subscription agreement was written. The note holders (the "Holders") would also receive, if any are 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.

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 restricted 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 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.

Kevin A. Richardson, II, chairman of the board of directors 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 warrants in the foregoing transaction.

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 embedded conversion feature was recorded at fair value and marked to market at each period, with the resulting change in fair value being recorded in the “loss on embedded conversion feature of Senior Secured Notes” in the accompanying condensed consolidated statements of comprehensive loss.

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

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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## 9. Notes payable, related parties

The notes payable, related parties consist of the following:

| | Sepetember 30, 2013 | December 31, 2012 |
|---|---|---|
| Notes payable, unsecured, payable to HealthTronics, Inc., a shareholder of the Company | $5,372,743 | $5,372,743 |
| Less current portion | - | - |
| Non-current portion | $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 $81,864 at September 30, 2013 and December 31, 2012, respectively.

Interest expense on notes payable to related parties totaled $81,864 and $81,864 for the three months ended September 30, 2013 and 2012, respectively, and $242,904 and $242,903 for the nine months ended September 30, 2013 and 2012, respectively.

## 10. 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, 2013, the Company had federal net operating loss ("NOL") carryforwards of $53,648,527 for tax years through the year ended December 31, 2012, 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, 2013 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2013. 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.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

## 11. Equity transactions

***2013 Private Offering***

On September 30, 2013, the Company, in conjunction with an offering of securities (previously defined as the "Private Offering") of the Company pursuant to an exemption from registration under the Act, issued 675,000 units (as described below) to certain "accredited investors," as that term is defined in SEC Rule 501 under the Act, for an aggregate total purchase price of $405,000. In addition, in October 2013, after the end of the third quarter of 2013, in conjunction with the Private Offering, the Company issued an additional 201,979 units for an aggregate total purchase price of $121,187. Each unit was sold to the accredited investors at a purchase price of $0.60 per unit. Each "unit" in the Private Offering consists of; (i) one share of common stock and (ii) a five-year common stock purchase warrant to purchase one share of common stock, at an exercise price of $0.85. The warrants are callable by the Company if the average share price of common stock of the Company is at or above $1.40 for a twenty day period.

Kevin A. Richardson II, who is the chairman of the board of directors of the Company, and Joseph Chiarelli, who is the Chief Executive Officer of the Company, and Michael M. Nemelka, who is the brother of John F. Nemelka, a member of the board of directors of the Company, purchased units in the Private Offering.

***2013 Public Offering***

On July 25, 2013, the Company consummated a public offering (as previously defined, the "Public Offering") of an aggregate of 3,006,818 units, with each unit consisting of one share of common stock and a warrant to purchase one-half share of a common stock, resulting in warrants to purchase up to 1,503,409 shares of common stock. The price per unit was $0.55 resulting in gross proceeds of $1,653,750. The Company received net proceeds, after payment of the placement agent's fees, of $1,517,450. The units separated immediately and the common stock and warrants were issued separately. The warrants have an exercise price of $0.80 per share and are exercisable during the five-year period beginning on the date of issuance.

***Consulting Agreements***

On February 25, 2013, the Company issued to a consultant 2,000,000 warrants to purchase the Company's common stock at $0.35 per share. The five year warrants vest 300,000 on the date of grant and 1,700,000 upon the completion of a $5,000,000, or greater, capital raise on or prior to June 8, 2013 (see Note 12). A capital raise was not completed for the requisite amount and the 1,700,000 warrants expired by their terms on June 8, 2013. The Company recorded the underlying cost of the 300,000 warrants as a cost of the Public Offering.

In February 2013, the Company entered into a consulting agreement with a consultant to assist the Company with its strategy for raising additional capital for which a portion of the fee for the services performed is common stock and warrants. The Company issued 100,000 shares of common stock under this agreement in February 2013. The fair value of the common stock of $35,000, based upon the closing market price of the Company's common stock at the date the common stock was issued, was recorded as consulting expense for the three months ended March 31, 2013. In addition, the Company committed to issue to the consultant 1,000,000 warrants to purchase common stock at an exercise price of $0.35 per share with a term of five years upon consummation by the Company of an qualified offering (as defined in the consulting agreement) resulting in gross proceeds to the Company of no less than $4,000,000. This agreement expired on July 29, 2013 and no warrants were earned or issued pursuant to the terms of the agreement.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**11. Equity transactions (continued)**

In February 2013, the Company entered into two consulting agreements for which a portion of the fee for the services performed is paid with common stock. In August and September 2013, the Company entered into two additional consulting agreements for which a portion of the fee for the services performed is paid with common stock. The Company issued 542,000 and 934,000 shares of common stock under these agreements for the three and nine months ended September 30, 2013, respectively. The fair value of the common stock of $313,880 and $622,760, based upon the closing market price of the Company's common stock at the dates the common stock was issued, was recorded as consulting expense for the three and nine months ended September 30, 2013, respectively.

**12. Warrants**

A summary of the warrant activity as of September 30, 2013 and December 31, 2012, and the changes during the three and nine months ended September 30, 2013, is presented as follows:

| | Class A Warrants | Class B Warrants | Class D Warrants | Class E Warrants | Class F Warrants | Class G Warrants | Class H Warrants | Class I Warrants |
|---|---|---|---|---|---|---|---|---|
| Outstanding as of December 31, 2012 | 1,106,627 | 1,106,627 | 1,950,167 | 3,576,737 | - | - | - | - |
| Issued | - | - | - | - | 2,000,000 | - | - | - |
| Exercised | - | - | - | - | - | - | - | - |
| Expired | - | - | (1,950,167) | - | - | - | - | - |
| Outstanding as of March 31, 2013 | 1,106,627 | 1,106,627 | - | 3,576,737 | 2,000,000 | - | - | - |
| Issued | - | - | - | - | - | - | - | - |
| Exercised | - | - | - | - | - | - | - | - |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Expired | - | - | - | - | - | - | - | - |
| Outstanding as of June 30, 2013 | 1,106,627 | 1,106,627 | - | 3,576,737 | 2,000,000 | - | - | - |
| Issued | - | - | - | - | - | 1,503,409 | 1,988,095 | 675,000 |
| Exercised | - | - | - | - | - | - | - | - |
| Expired | - | - | - | - | (1,700,000) | - | - | - |
| Outstanding as of September 30, 2013 | 1,106,627 | 1,106,627 | - | 3,576,737 | 300,000 | 1,503,409 | 1,988,095 | 675,000 |

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**12. Warrants (continued)**

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

| | Class A Warrants | Class B Warrants | Class D Warrants | Class E Warrants | Class F Warrants | Class G Warrants | Class H Warrants | Class I Warrants |
|---|---|---|---|---|---|---|---|---|
| Exercise price/share | $ 4.00 | $ 8.00 | $ 2.00 | $ 4.00 | $ 0.35 | $ 0.80 | $ 0.80 | $ 0.85 |
| Expiration Date | September 2014 | September 2014 | January 2013 | April 2016 | February 2018 | July 2018 | July 2018 | September 2018 |

The exercise price and the number of shares covered by the warrants will be adjusted if the Company has a stock split, if there is a recapitalization of the Company's common stock, or if the Company consolidates with or merges into another company.

As discussed in Note 11 above, on February 25, 2013, the Company issued 2,000,000 warrants to a consultant to purchase the Company's common stock at $0.35 per share. The five year warrants vest 300,000 on the date of grant and 1,700,000 upon the completion of a $5,000,000, or greater, capital raise on or prior to June 8, 2013. A capital raise was not completed for the requisite amount and the 1,700,000 warrants expired by their terms. The Company recorded the underlying cost of the 300,000 warrants as a cost of the Public Offering.

**13. Commitments and contingencies**

***Subscription agreement***

On November 27, 2012, the Company and David N. Nemelka (the "Subscriber"), the brother of John F. Nemelka, a member of the Company's board of directors, entered into a subscription agreement (the "Subscription Agreement") whereby the Subscriber has 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 shall be 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 may 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 shall, upon demand of the Company, pay to the Company $100,000 of the then outstanding balance of the Purchase Price, which payment shall be due within thirty (30) days of the demand. There is no limit on the number of demands that the Company may make pursuant to this provision of the Subscription Agreement, provided, however, that in no event shall the Company provide more than one notice of demand for payment in any thirty (30) day period.

As of September 30, 2013, the Subscriber had paid the Company $100,000 and was issued 400,000 shares of unregistered common stock of the Company. The Company will record the additional $900,000 and issue the corresponding 3,600,000 shares of common stock in the periods in which the Purchase Price is received.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**13. Commitments and contingencies (continued)**

***Operating Leases***

Rent expense for the three months ended September 30, 2013 and 2012, was $22,531 and $68,462, respectively, and $76,508 and $238,712 for the nine months ended September 30, 2013 and 2012, respectively.

***Capital Leases***

The Company leases certain office equipment under an agreement classified as a capital lease. The leased assets serve as security for the lease. The accumulated depreciation of such equipment at September 30, 2013 and December 31, 2012 totaled $10,106 and $6,468, respectively. The net book value of such equipment at September 30, 2013 and December 31, 2012 totaled $4,446 and $8,085, 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.

**14. 401(k) plan**

The Company sponsors a 401(k) plan that covers all employees who meet the eligibility requirements. The Company amended the 401(k) plan to make the Company matching contribution discretionary and discontinued the Company match effective February 1, 2012. The Company did not contribute to the plan for the three months ended September 30, 2013 and 2012, respectively. The Company contributed $0 and $9,664 to the plan for the nine months ended September 30, 2013 and 2012, respectively.

**15. Stock-based compensation**

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the “Stock Incentive Plan”). The Stock Incentive Plan permits grants of awards to selected employees, directors and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is currently administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are non-statutory options which generally vest over a period of up to 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 December 31, 2012, the Stock Incentive Plan reserved 5,000,000 shares of common stock for grant. On February 21, 2013, the Stock Incentive Plan was amended to reserve a total of 8,500,000 shares of common stock for grant.

On September 3, 2013, the Company granted 100,000 options to the new member of the board of directors at an exercise price of $0.65 per share. The options vested at the date of grant and have a ten year term. Using the Black-Scholes option pricing model, management has determined that the options had a weighted average fair value per share of $0.60 resulting in total compensation of $60,000. Compensation cost was recognized at grant date.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**15. Stock-based compensation (continued)**

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 will be 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 $0.63 resulting in compensation expense of $63,000. Compensation cost will be recognized over the calendar year 2013.

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 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 has 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.

On March 8, 2012, 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 $0.44 per share in place of an annual

cash consulting fee for calendar year 2012. Using the Black-Scholes option pricing model, management has determined that the options granted had a fair value per share of $0.27 resulting in total compensation of $27,250. Compensation cost was recognized over the calendar year 2012.

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 three months ended September 30, 2013 and 2012:

| | 2013 | 2012 |
|---|---|---|
| Weighted average expected life in years | 5.0 | 5.2 |
| Weighted average risk free interest rate | 1.68 % | 0.95% |
| Weighted average volatility | 149.0% | 75.0% |
| Forfeiture rate | 0.0 % | 0.0 % |
| Expected dividend yield | 0.0 % | 0.0 % |

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**15. Stock-based compensation (continued)**

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, $175,987 and $217,686 for the three months ended September 30, 2013 and 2012, respectively, and $683,382 and $719,732 for the nine months ended September 30, 2013 and 2012, respectively.

A summary of option activity as of September 30, 2013 and December 31, 2012, and the changes during the three and nine months ended September 30, 2013, is presented as follows:

| | Options | Weighted Average Exercise Price per share |
|---|---|---|
| Outstanding as of December 31, 2012 | 5,229,330 | $ 2.25 |
| Granted | 4,593,644 | $ 0.35 |
| Exercised | - | $ - |
| Cancelled | (1,113,644) | $ 2.92 |

| | | |
|---|---|---|
| Forfeited or expired | (105,000 ) | $ 2.93 |
| Outstanding as of March 31, 2013 | 8,604,330 | $ 1.14 |
| Granted | - | $ - |
| Exercised | (108,334 ) | $ 0.35 |
| Cancelled | - | $ - |
| Forfeited or expired | (229,166 ) | $ (0.34 ) |
| Outstanding as of June 30, 2013 | 8,266,830 | $ 1.17 |
| Granted | 100,000 | $ 0.65 |
| Exercised | - | $ - |
| Cancelled | - | $ - |
| Forfeited or expired | - | $ - |
| Outstanding as of September 30, 2013 | 8,366,830 | $ 1.17 |
| | | |
| Exercisable | 4,887,738 | $ 1.76 |

The weighted average remaining contractual term for outstanding and exercisable stock options was 7.1 years as of September 30, 2013, and 6.6 years as of December 31, 2012.

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**15. Stock-based compensation (continued)**

A summary of the Company's nonvested options as of September 30, 2013 and December 31, 2012, and changes during the three and nine months ended September 30, 2013, is presented as follows:

| | Options | Weighted Average Exercise Price per share |
|---|---|---|
| Outstanding as of December 31, 2012 | 508,750 | $ 0.66 |
| Granted | 4,593,644 | $ 0.35 |
| Vested | (1,180,386) | $ 0.41 |
| Cancelled | (43,750) | $ 2.87 |
| Forfeited or expired | (7,500) | $ 5.25 |
| Outstanding as of March 31, 2013 | 3,870,758 | $ 0.33 |
| Granted | - | $ - |
| Vested | (137,500) | $ 0.24 |
| Cancelled | - | $ - |
| Forfeited or expired | (229,166) | $ 0.34 |
| Outstanding as of June 30, 2013 | 3,504,092 | $ 0.34 |
| Granted | 100,000 | $ 0.65 |
| Vested | (125,000) | $ 0.59 |
| Cancelled | - | $ - |
| Forfeited or expired | - | $ - |
| Outstanding as of September 30, 2013 | 3,479,092 | $ 0.34 |

**16. Changes in other comprehensive loss**

The amounts recognized in other comprehensive loss for the three and nine months ended September 30, 2013 were as follows:

| | Currency Translations | Total |
|---|---|---|
| Balance, at December 31, 2012 | $ 13,116 | $13,116 |
| Other comprehensive loss before reclassifications | (6,925) | (6,925) |
| Amounts reclassified from AOCI | - | - |
| Net change in other comprehensive loss | (6,925) | (6,925) |
| Balance, at March 31, 2013 | 6,191 | 6,191 |
| Other comprehensive income | 2,950 | 2,950 |
| Balance, at June 30, 2013 | 9,141 | 9,141 |
| Other comprehensive loss | (1,829) | (1,829) |
| Balance, at September 30, 2013 | $ 7,312 | $7,312 |

**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2013**

**17. 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, 2013 and 2012, 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 18,623,325 shares and 14,189,481 shares at September 30, 2013 and 2012, 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, 2012 included in our Annual Report on Form 10-K, filed with the SEC on March 26, 2013.*

**Overview**

We are a shockwave technology company using our patented noninvasive, high-energy, acoustic shockwaves for regenerative medicine and other applications. Our initial focus is regenerative medicine – utilizing noninvasive, acoustic shockwaves to solicit a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal and vascular structures. Our lead regenerative product in the United States is the dermaPACE device, which is in a supplemental Phase III clinical study for treating diabetic foot ulcers with possible FDA approval in 2015 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. Our Pulsed Acoustic Cellular Expression (PACE) technology is being applied in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. We generate our revenue from sales of the CE Mark devices and accessories in Europe, Canada and Asia/Pacific. We are not currently marketing any commercial products in the United States.

In addition, we believe there are significant license/partnership opportunities for our shockwave technology in non-medical uses, including energy, water, food and industrial markets, and we believe we have a broad intellectual property portfolio and broad know-how.

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

- wound conditions, including diabetic foot ulcers, venous ulcers, pressure sores, burns and other skin eruption conditions;
- orthopedic applications, such as eliminating chronic pain in joints from trauma or arthritis, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;
- plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and
- cardiac applications for removing plaque due to atherosclerosis and improving heart muscle performance.

In addition to healthcare uses, our patented high-energy, acoustic pressure shockwaves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids and finally for maintenance of industrial installations by disrupting the formation of biofilms. We are seeking to exploit such potential uses 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 we have enrolled over 50% of the minimum number of ninety patients in the clinical trial. Management expects to complete the enrollment phase of the clinical study in the first quarter of 2014 with patient follow-up for efficacy completed in the second quarter of 2014 and top-line data available in the summer of 2014.

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 addition, in the current trial up to four additional dermaPACE procedures are delivered bi-weekly, between weeks 4 and 10, 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 additional study, substantially fewer patients should be required than would otherwise be the case while still ensuring adequate statistical power. This approach will save significant time and preserve scientific rigor.

The supplemental clinical study also incorporates an independent group of medical professionals who will 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.

Importantly, the study design allows for controlled interim monitoring of the data by an independent Data Monitoring Committee (DMC) to determine whether study success has been achieved. We anticipate that the first analysis of the success of the study will occur after 90 patients (approximately 45 per arm) have completed the 12-week primary efficacy evaluation period. If study data achieves pre-defined statistical and clinical success criteria associated with wound closure favoring dermaPACE, then the clinical trial can be stopped, and we will submit a PMA for approval. The controlled interim monitoring plan also includes a provision for DMC review of data prior to enrollment of the 90 subjects. This provision has been established in order to monitor the progress of the trial and ensure its alignment with our statistical plan, or to increase the sample size should additional subjects be needed to demonstrate study success, or stop the trial if study success is deemed unattainable. By monitoring the data in this way, we can take appropriate steps to allocate resources based on the direction the data is heading, prior to arriving at the 90 patient mark, which is the first point at which study success may be determined per our agreement with the FDA.

*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 June 2011. The primary study goal was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared to sham-control, when both are combined with the current standard of care. 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 are 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 intent-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 ≥90% wound closure. We analyzed a clinically relevant ≥ 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 procedure, 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 our inception in 2005, we have funded our operations from the sale of capital stock, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009, and product sales. At September 30, 2013, our balance of cash and cash equivalents totaled $333,830 and we had a net working capital deficit of $1,698,241.

On September 30, 2013, in conjunction with an offering of securities in the Private Offering pursuant to an exemption from registration under the Act, we issued 675,000 units (as described below) to certain accredited investors for an aggregate total purchase price of $405,000. In addition, in October 2013, after the end of the third quarter of 2013, in conjunction with the Private Offering, we issued an additional 201,979 units for an aggregate total purchase price of $121,187. Each unit was sold at a purchase price of $0.60 per unit with each "unit" consisting of; (i) one share of common stock and (ii) a five-year warrant to purchase one share of common stock at an exercise price of $0.85.

On July 25, 2013, we consummated a Public Offering of an aggregate of 3,006,818 units, with each unit consisting of one share of common stock and a warrant to purchase one-half share of a common stock, resulting in warrants to purchase up to 1,503,409 shares of common stock. The price per unit was $0.55 resulting in gross proceeds of $1,653,750. We received net proceeds, after payment of the placement agent's fees, of $1,517,450. The units separated immediately and the common stock and warrants were issued separately. The warrants have an exercise price of $0.80 per share and are exercisable during the five-year period beginning on the date of issuance.

The continuation of our business is dependent upon raising additional capital in the fourth quarter of 2013. Management's plans are to obtain additional capital in the fourth quarter of 2013 through the issuance of common stock and/or other debt or equity securities and we have engaged financial advisors to assist with this process. Our cash and cash equivalents at September 30, 2013, combined with the proceeds from the Private Offering in October 2013, and/or amounts received on the subscription agreement with an affiliated shareholder will support our operations through the completion, in the fourth quarter of 2013, of an anticipated capital raise as discussed above. Management expects the monthly use of cash in the fourth quarter of 2013 and the first half of 2014 will be approximately $575,000 to $625,000 as we devote substantial resources to the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers. Management estimates the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

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 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.

We will require additional capital in the fourth quarter of 2013 to continue as a going concern. There can be no assurance that we will be successful in raising such capital.

Since our inception, we have incurred losses from operations each year. As of September 30, 2013, we had an accumulated deficit of $81,534,776. 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, 2012, filed with the SEC on March 26, 2013.

**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, the estimated fair value of intangible assets and the estimated fair value assigned to the common stock and warrants issued for consulting agreements. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements filed with our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 26, 2013, 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 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, quality control, 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, 2013 and 2012 (Unaudited)**

*Revenue and Cost of Revenue*

Revenue for the three months ended September 30, 2013 was $148,421, compared to $178,256 for the same period in 2012, a decrease of $29,835, or 17%. The decrease in revenue for 2013 was primarily due to the one-time sale in 2012 of new device applicators to a distributor in Asia.

Cost of revenue for the three months ended September 30, 2013 was $29,467, compared to $43,965 for the same period in 2012. Gross profit as a percentage of revenue was 80% for the three months ended September 30, 2013, as compared to 75% for the same period in 2012. The increase in gross profit as a percentage of revenue in 2013 was due to increased sales of higher margin refurbishment applicators in 2013, as compared to 2012.

*Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2013 were $775,717, compared to $440,193 for the same period in 2012, an increase of $335,524, or 76%. Research and development expenses in 2013 included $472,840 in expenses associated with the dermaPACE clinical trial including the costs for our clinical research organization, the clinical site costs related to the patients enrolled during the quarter and the costs of non-capital software and equipment used by the clinical trial sites as compared to $46,718 for the same period in 2012. This increase in expenses was offset by the reductions in headcount in November 2012 which resulted in a decrease in expense in 2013, as compared to the prior period in 2012, of $102,101.

*General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2013 were $1,151,709, compared to $977,859 for the same period in 2012, an increase of $173,850, or 18%. General and administrative expenses include non-cash stock-based compensation of $154,753 and $217,686 for the three months ended September 30, 2013 and 2012, respectively, and non-cash cost for stock issued for consulting services of $407,707 and $0 for the three months ended September 30, 2013 and 2012, respectively. The increase in non-cash cost for stock issued for consulting services was primarily due to financial and investors relations consultants utilized in 2013.

Excluding the non-cash costs for stock-based compensation and consulting services above, general and administrative expenses were $589,249 for the three months ended September 30, 2013, as compared to $760,173 for the same period in 2012, a decrease of $170,924, or 22%. The decrease in general and administrative expenses is primarily due to a reduction in headcount in November 2012 which resulted in a decrease in expense in 2013, as compared to 2012.

*Other Income (Expense)*

Other income (expense) was a net expense of $2,546,775 for the three months ended September 30, 2013 as compared to a net expense of $81,848 for the same period in 2012, an increase in the net expense of $2,464,927. The increase in the net expense for 2013 was due to a non-cash loss 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, 2013, we had federal net operating loss carryforwards of $53,648,527 for tax years through the year ended December 31, 2012 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. 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. We recorded a full valuation allowance as of September 30, 2013 and 2012, due to uncertainties related to our ability to utilize our deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire.

*Net Loss*

Net loss for the three months ended September 30, 2013 was $4,436,790, or ($0.14) per basic and diluted share, compared to a net loss of $1,447,271, or ($0.07) per basic and diluted share, for the same period in 2012, an increase in the net loss of $2,989,519, or 207%. The increase in the net loss was primarily a result of the $2,464,927 increase in the primarily non-cash expense in other income (expense) for 2013, as compared to 2012, for the accounting for the Senior Secured Notes which were converted into equity during the quarter and the increase in research and development expenses for clinical study related costs of $426,122 as a result of the start of the enrollment phase of the dermaPACE clinical trial for treating diabetic foot ulcers in 2013.

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.

**Results of Operations for the Nine Months ended September 30, 2013 and 2012 (Unaudited)**

*Revenue and Cost of Revenue*

Revenue for the nine months ended September 30, 2013 was $510,272, compared to $627,153 for the same period in 2012, a decrease of $116,881, or 19%. The decrease in revenue for 2013 is due to lower sales of orthoPACE devices in Europe for orthopedic, trauma and sports medicine indications due to the European economic downturn. This is partially offset by an increase in sales of applicators for 2013 as a result of more devices in use.

Cost of revenue for the nine months ended September 30, 2013 was $109,061, compared to $197,898 for the same period in 2012. Gross profit as a percentage of revenue was 79% for the nine months ended September 30, 2013, as compared to 68% for the same period in 2012. The increase in gross profit as a percentage of revenue in 2013 was due to increased sales of higher margin applicators in 2013, as compared to 2012, and fewer sales of lower margin demonstration devices in 2013, as compared to 2012.

*Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2013 were $1,744,935, compared to $1,391,634 for the same period in 2012, an increase of $353,301, or 25%. Research and development expenses in 2013 included $916,906 in expenses associated with the dermaPACE clinical trial including the costs for our clinical research organization, the clinical site costs related to the patients enrolled during the quarter and the costs of non-capital software and equipment used by the clinical trial sites as compared to $97,244 for the same period in 2012. This increase in expenses was offset by the reductions in headcount in November 2012 which resulted in a decrease in expense in 2013, as compared to the prior period in 2012, of $497,402.

*General and Administrative Expenses*

General and administrative expenses for the nine months ended September 30, 2013 were $3,160,749, compared to $3,252,127 for the same period in 2012, a decrease of $91,378, or 3%. General and administrative expenses include non-cash stock-based compensation of $548,595 and $719,732 for the nine months ended September 30, 2013 and 2012, respectively, and non-cash cost for stock issued for consulting services of $751,587 and $0 for the nine months ended September 30, 2013 and 2012, respectively. The increase in non-cash cost for stock issued for consulting services was primarily due to financial and investors relations consultants utilized in 2013.

Excluding the non-cash costs for stock-based compensation and consulting services above, general and administrative expenses were $1,860,567 for the nine months ended September 30, 2013, as compared to $2,532,395 for the same period in 2012, a decrease of $671,828, or 27%. The decrease in general and administrative expenses is primarily due to a reduction in headcount in November 2012 which resulted in a decrease in expense in 2013, as compared to 2012.

*Other Income (Expense)*

Other income (expense) was a net expense of $5,875,078 for the nine months ended September 30, 2013 as compared to a net expense of $247,326 for the same period in 2012, an increase of $5,627,752 in the net expense. The increase in the net expense in 2013 was due to a non-cash loss of $2,373,813 for the embedded conversion feature of the Senior Secured Notes which were converted to equity during the third quarter of 2013, 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 $2,178,390 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, 2013, we had federal net operating loss carryforwards of $53,648,527 for tax years through the year ended December 31, 2012 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. 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. We recorded a full valuation allowance as of September 30, 2013 and 2012, due to uncertainties related to our ability to utilize our deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire.

*Net Loss*

Net loss for the nine months ended September 30, 2013 was $10,624,454, or ($0.43) per basic and diluted share, compared to a net loss of $4,707,212, or ($0.23) per basic and diluted share, for the same period in 2012, an increase in the net loss of $5,917,242, or 126%. The increase in the net loss was primarily a result of the primarily non-cash increase in the net expense in other income (expense) of $5,627,752 for 2013, as compared to 2012, for the accounting for the Senior Secured Notes which were converted to equity in the third quarter of 2013 and by the increase in research and development expenses as a result of the start of the enrollment phase of the dermaPACE clinical trial for treating diabetic foot ulcers in 2013.

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.

**Liquidity and Capital Resources**

The continuation of our business is dependent upon raising additional capital in the fourth quarter of 2013. Management's plans are to obtain additional capital in the fourth quarter of 2013 through the issuance of common stock and/or other debt or equity securities and we have engaged financial advisors to assist with this process. Our cash and cash equivalents at September 30, 2013, combined with the proceeds from the Private Offering in October 2013, and/or amounts received on our subscription agreement with an affiliated shareholder are expected to support the Company's operations through the completion, in the fourth quarter of 2013, of an anticipated capital raise as discussed above. Management expects our monthly use of cash in the fourth quarter of 2013 and the first half of 2014 will be approximately $575,000 to $625,000 as we devote substantial resources to the patient enrollment phase of the supplemental Phase III clinical trial for the dermaPACE device to treat diabetic foot ulcers. Management estimates the direct cost of the dermaPACE clinical trial will be approximately $3,800,000 through 2014.

As of September 30, 2013, we had cash and cash equivalents of $333,830 and negative working capital of $1,698,241. For the nine months ended September 30, 2013 and 2012, the net cash used by operating activities was $3,374,894 and $3,546,299, respectively. We incurred a net loss of $10,624,454 for the nine months ended September 30, 2013 and a net loss of $6,401,494 for the year ended December 31, 2012.

On September 30, 2013, in conjunction with an offering of securities in the Private Offering pursuant to an exemption from registration under the Act, we issued 675,000 units (as described below) to certain accredited investors for an aggregate total purchase price of $405,000. In addition, in October 2013, after the end of the third quarter of 2013, in conjunction with the Private Offering, we issued an additional 201,979 units for an aggregate total purchase price of $121,187. Each unit was sold at a purchase price of $0.60 per unit with each "unit" consisting of; (i) one share of

common stock and (ii) a five-year warrant to purchase one share of common stock at an exercise price of $0.85.

On July 25, 2013, we consummated a Public Offering of an aggregate of 3,006,818 units, with each unit consisting of one share of common stock and a warrant to purchase one-half share of a common stock, resulting in warrants to purchase up to 1,503,409 shares of common stock. The price per unit was $0.55 resulting in gross proceeds of $1,653,750. We received net proceeds, after payment of the placement agent's fees, of $1,517,450. The units separated immediately and the common stock and warrants were issued separately. The warrants have an exercise price of $0.80 per share and are exercisable during the five-year period beginning on the date of issuance.

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 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.

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, 2013 and 2012, net cash used by operating activities was $3,374,894 and $3,546,299, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for 2013, as compared to the same period for 2012, of $171,405, or 5%, was primarily due to reductions in headcount in November 2012 which resulted in decreased operating expenses in 2013, as compared to 2012, partially offset by the increase in research and development expenses for clinical study related costs as a result of the start of the enrollment phase of the dermaPACE clinical trial for treating diabetic foot ulcers in 2013. Net cash provided (used) by financing activities for the nine months ended September 30, 2013 and 2012 was $3,636,703 and ($3,399), respectively, which in 2013 primarily consisted of the net proceeds from the subscriptions payable for Senior Secured Notes of $1,570,000, net proceeds from the Public Offering of $1,517,450 and proceeds from the Private Offering of $405,000. Cash and cash equivalents increased by $263,505 for the nine months ended September 30, 2013. Cash and cash equivalents decreased by $3,548,120 for the nine months ended September 30, 2012.

**Segment and Geographic Information**

We have determined that we are principally engaged in one operating segment. Our product candidates are primarily used for the repair and regeneration of tissue, musculoskeletal and vascular structures in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. Our revenues are generated from sales in Europe, Canada and Asia/Pacific. We are not currently marketing any commercial products in the United States.

**Contractual Obligations**

Our major outstanding contractual obligations relate to our operating leases for our facilities, 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, as filed with the SEC on March 26, 2013.

**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 condensed 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 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, 2013. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2013.

**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.

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**PART II — OTHER INFORMATION**

**Item 6. EXHIBITS**

| Exhibit No. | Description |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009). |
| 3.1 | Articles of Incorporation (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007). |
| 3.2 | Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009). |
| 3.3 | Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012). |
| 3.4 | Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007). |
| 4.1 | Form of Subscription Agreement issued by SANUWAVE Health, Inc. (Incorporated by reference to Form 8-K filed with the SEC on October 3, 2013). |
| 31.1* | Rule 13a-14(a)/15d-14(a) Certification of the Principal Executive Officer. |
| 31.2* | Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer. |
| 32.1* | Section 1350 Certification of the Principal Executive Officer. |
| 32.2* | Section 1350 Certification of the Chief Financial Officer. |
| 101.INS** | XBRL Instance. |
| 101.SCH** | XBRL Taxonomy Extension Schema. |
| 101.CAL** | XBRL Taxonomy Extension Calculation. |
| 101.DEF** | XBRL Taxonomy Extension Definition. |
| 101.LAB** | XBRL Taxonomy Extension Labels. |
| 101.PRE** | XBRL Taxonomy Extension Presentation. |

* Filed herewith.

** 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.

**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, 2013

**SANUWAVE HEALTH, INC.**

By: /s/ Joseph Chiarelli

**Joseph Chiarelli**

Chief Executive Officer

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

| **Signatures** | **Capacity** | **Date** |
|---|---|---|
| By: */s/ Joseph Chiarelli*<br>Name: Joseph Chiarelli | Chief Executive Officer and Director<br>(principal executive officer) | November 12, 2013 |
| By: */s/ Barry J. Jenkins*<br>Name: Barry J. Jenkins | Chief Financial Officer (principal financial and accounting officer) | November 12, 2013 |

| | | |
|---|---|---|
| By: */s/Kevin A. Richardson, II* | | |
| Name: Kevin A. Richardson, II | Chairman of the Board of Directors | November 12, 2013 |
| By*: /s/ John F. Nemelka* | | |
| Name: John F. Nemelka | Director | November 12, 2013 |
| By*: /s/ Alan L. Rubino* | | |
| Name: Alan L. Rubino | Director | November 12, 2013 |

**EXHIBIT INDEX**

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