

RUB MUSIC ENTERPRISES, INC.

Form 10-Q

November 16, 2009

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**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, 2009**

☐ **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**

(State or other jurisdiction of  
incorporation or organization)

**20-1176000**

(I.R.S. Employer  
Identification No.)

**11680 Great Oaks Way, Suite 350**

**Alpharetta, GA**

(Address of principal executive offices)

**30022**

(Zip Code)

**(678) 581-6843**

(Registrant's telephone number, including area code)

**Rub Music Enterprises, Inc.**

(Former name, former address and former fiscal year, if changed  
since last report)

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 16, 2009, there were issued and outstanding 12,509,657 shares of the registrant's common stock.



**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 (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, 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, predict, potential and continue, the 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 this report, including the sections titled Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations. Other risks and uncertainties are disclosed in the Company's prior Securities and Exchange Commission 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 Current Report on Form 8-K filed on September 30, 2009.

*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.*

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)

	September 30, 2009	December 31, 2008
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,297,436	\$ 543,626
Accounts receivable trade, net of allowance for doubtful accounts of \$26,363 in 2009 and \$64,490 in 2008	87,384	52,414
Inventory (Note 7)	584,572	684,750
Prepaid expenses	56,364	106,617
Due from Pulse Veterinary Technologies, LLC	167,990	
Current assets related to discontinued operations (Note 6)	168,509	1,285,017
<b>TOTAL CURRENT ASSETS</b>	<b>4,362,255</b>	<b>2,672,424</b>
<b>PROPERTY AND EQUIPMENT</b> , at cost, less accumulated depreciation (Note 8)	<b>136,891</b>	<b>279,791</b>
<b>OTHER ASSETS</b>	<b>63,261</b>	<b>81,017</b>
<b>INTANGIBLE ASSETS</b> , at cost, less accumulated amortization (Note 9)	<b>2,223,984</b>	<b>2,454,051</b>
<b>NON-CURRENT ASSETS RELATED TO DISCONTINUED OPERATIONS</b> (Note 6)	<b>924,971</b>	<b>1,011,734</b>
<b>TOTAL ASSETS</b>	<b>\$ 7,711,362</b>	<b>\$ 6,499,017</b>
<b>LIABILITIES</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,233,942	\$ 975,811
Payroll and related	511,770	820,397
Accrued expenses	350,744	448,242
Liabilities related to discontinued operations (Note 6)	655,761	845,593
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,752,217</b>	<b>3,090,043</b>
<b>NOTES PAYABLE, RELATED PARTIES</b> (Note 11)	<b>8,659,554</b>	<b>6,006,815</b>
<b>TOTAL LIABILITIES</b>	<b>11,411,771</b>	<b>9,096,858</b>

COMMITMENTS AND CONTINGENCIES (Note 12)

	STOCKHOLDERS EQUITY (DEFICIT)	
COMMON STOCK	12,510	11,500
ADDITIONAL PAID-IN CAPITAL	32,248,865	30,094,546
ACCUMULATED OTHER COMPREHENSIVE LOSS	(4,081)	(196,646)
RETAINED DEFICIT	(35,957,703)	(32,507,241)
TOTAL STOCKHOLDERS EQUITY (DEFICIT)	(3,700,409)	(2,597,841)
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)	\$ 7,711,362	\$ 6,499,017

See accompanying notes to unaudited condensed consolidated  
financial statements.

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(UNAUDITED)

	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
REVENUES	\$ 134,771	\$ 167,423	\$ 538,818	\$ 862,651
COST OF REVENUES	30,753	60,213	129,416	281,948
GROSS PROFIT	104,018	107,210	409,402	580,703
OPERATING EXPENSES				
Research and development	1,063,876	865,518	2,686,160	2,396,185
General and administrative	1,530,282	1,935,750	3,433,448	6,027,089
Depreciation	46,636	70,031	150,482	193,602
Amortization	76,689	76,689	230,067	230,067
TOTAL OPERATING EXPENSES	2,717,483	2,947,988	6,500,157	8,846,943
OPERATING LOSS	(2,613,465)	(2,840,778)	(6,090,755)	(8,266,240)
OTHER INCOME (EXPENSE)				
Gain/(loss) on sale of assets	9,142		(4,509)	
Transitional services provided to Pulse Veterinary Technologies, LLC	102,500		136,250	
Interest expense	(188,278)	(72,552)	(517,354)	(213,042)
Loss on foreign currency exchange	(6,654)	(4,129)	(44,428)	(29,135)
TOTAL OTHER INCOME (EXPENSE)	(83,290)	(76,681)	(430,041)	(242,177)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(2,696,755)	(2,917,459)	(6,520,796)	(8,508,417)
INCOME TAX EXPENSE				
	(2,696,755)	(2,917,459)	(6,520,796)	(8,508,417)

# LOSS FROM CONTINUING OPERATIONS

## DISCONTINUED OPERATIONS

Income from discontinued operations, net of tax		565,534	581,306	684,662
Gain/(loss) on sale of veterinary division, net of tax	(3,245)		2,489,028	

NET INCOME (LOSS) FROM DISCONTINUED OPERATIONS	(3,245)	565,534	3,070,334	684,662
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NET LOSS	(2,700,000)	(2,351,925)	(3,450,462)	(7,823,755)
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## OTHER COMPREHENSIVE INCOME (LOSS), net of tax

Foreign currency translation adjustments	12,031	(135,365)	(33,671)	(52,363)
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TOTAL COMPREHENSIVE LOSS	\$ (2,687,969)	\$ (2,487,290)	\$ (3,484,133)	\$ (7,876,118)
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## EARNINGS (LOSS) PER SHARE:

Loss from continuing operations basic	\$ (0.23)	\$ (0.26)	\$ (0.56)	\$ (0.79)
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Loss from continuing operations diluted	\$ (0.23)	\$ (0.26)	\$ (0.56)	\$ (0.79)
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Income (loss) from discontinued operations basic	\$ (0.00)	\$ 0.05	\$ 0.26	\$ 0.06
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Income (loss) from discontinued operations diluted	\$ (0.00)	\$ 0.05	\$ 0.26	\$ 0.06
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Net loss basic	\$ (0.23)	\$ (0.21)	\$ (0.30)	\$ (0.73)
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Net loss diluted	\$ (0.23)	\$ (0.21)	\$ (0.30)	\$ (0.73)
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Weighted average shares outstanding basic	11,836,552	11,383,932	11,612,184	10,798,162
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Weighted average shares outstanding diluted	11,836,552	11,383,932	11,612,184	10,798,162
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See accompanying notes to unaudited condensed consolidated financial statements.



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SANUWAVE HEALTH, INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
 (UNAUDITED)

	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss from continuing operations	\$ (6,520,796)	\$ (8,508,417)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization	230,067	230,067
Accrued interest	527,739	213,051
Depreciation	150,482	193,602
Change in allowance for doubtful accounts	(38,128)	7,620
Loss on sale of property and equipment	4,509	
Stock-based compensation	585,400	401,088
Changes in assets (increase)/decrease		
Accounts receivable trade	3,158	13,447
Inventory	100,178	(35,342)
Prepaid expenses	50,253	189,917
Due from Pulse Veterinary Technologies, LLC	(167,990)	
Other assets	17,756	62,439
Changes in liabilities increase/(decrease)		
Accounts payable	258,131	(122,043)
Payroll and related	(308,627)	(46,071)
Accrued expenses	(97,498)	(312,044)
<b>NET CASH USED BY CONTINUING OPERATIONS</b>	(5,205,366)	(7,712,686)
<b>NET CASH PROVIDED BY DISCONTINUED OPERATIONS</b>	708,237	2,151,826
<b>NET CASH USED BY OPERATING ACTIVITIES</b>	(4,497,129)	(5,560,860)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Continuing operations		
Proceeds from sale of property and equipment	9,142	
Purchase of property and equipment	(21,233)	(124,917)
<b>NET CASH PROVIDED (USED) BY CONTINUING OPERATIONS</b>	(12,091)	(124,917)
<b>NET CASH PROVIDED BY DISCONTINUED OPERATIONS</b>	3,601,772	8,858
<b>NET CASH PROVIDED (USED) BY INVESTING ACTIVITIES</b>	3,589,681	(116,059)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Continuing operations		

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Proceeds from notes payable, related parties	2,125,000	
Proceeds from sale of stock	1,819,844	5,675,000
Repurchase of stock	(180,000)	
Payment of development period liabilities	(69,915)	
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,694,929	5,675,000
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS	(33,671)	(52,363)
NET INCREASE (DECREASE) IN CASH	2,753,810	(54,282)
CASH, BEGINNING OF PERIOD	543,626	693,033
CASH, END OF PERIOD	\$ 3,297,436	\$ 638,751

See accompanying notes to unaudited condensed consolidated  
financial statements.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2009**

**1. Nature of the Business**

SANUWAVE Health, Inc. and subsidiaries (the Company) is a global medical technology company which through its wholly owned subsidiary SANUWAVE, Inc. (SANUWAVE) is focused on the development and utilization of Pulsed Acoustic Cellular Expression (PACE) technology for advanced wound care, orthopedic/spine, plastic/cosmetic and cardiac conditions.

**2. Basis of Presentation and Principles of Consolidation**

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 10 of Regulation S-X. Accordingly, these 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, 2009 and for the three and nine months ended September 30, 2009 and 2008 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, 2009 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2009.

The condensed consolidated balance sheet at December 31, 2008 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.

For further information and a summary of significant accounting policies, refer to the consolidated financial statements and footnotes thereto included in the Company's Current Report on Form 8-K filed on September 30, 2009. Please refer also to Note 4 regarding the Company's adoption of recent accounting pronouncements.

**3. Reverse Merger Transaction**

On September 25, 2009, SANUWAVE Health, Inc. (formerly named Rub Music Enterprises, Inc. (SANUWAVE Health)) and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of SANUWAVE Health (the Merger Sub), entered into a reverse merger agreement (the Merger Agreement) with SANUWAVE. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, with SANUWAVE as the surviving entity (the Merger). In connection with the Merger, SANUWAVE Health acquired 100% of the outstanding capital stock of SANUWAVE and the stockholders of SANUWAVE received 11,009,657 shares of the SANUWAVE Health's common stock, warrants to purchase 1,106,627 shares of SANUWAVE Health's common stock at \$4.00 per share, and warrants to purchase an additional 1,106,627 shares of SANUWAVE Health's common stock at \$8.00 per share. In addition, in connection with the Merger, certain stockholders of SANUWAVE Health agreed to cancel all of their shares of common stock of SANUWAVE Health, except for 1,500,000 shares of common stock, for an aggregate price of \$180,000 (the Share Repurchase). At the time of the Merger, SANUWAVE Health had 1,500,000 warrants outstanding to purchase SANUWAVE Health's common stock at \$4.00 per share.

As a result of the Merger and Share Repurchase, the stockholders of SANUWAVE control approximately 88% of SANUWAVE Health's outstanding common stock, holding 11,009,657 of the 12,509,657 outstanding shares, and SANUWAVE is considered the accounting acquirer in this Merger. SANUWAVE Health was a shell company as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act) immediately prior to the Merger. As a result of the Merger, SANUWAVE Health's operations are now focused in global medical technology. Consequently, SANUWAVE Health believes that the Merger has caused the Company to cease being a shell company as it no longer has nominal operations.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**4. Recent Accounting Pronouncements**

***The FASB Accounting Standards Codification***

In June 2009, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* ( SFAS No. 168 ), which establishes the FASB Accounting Standards Codification ( Codification ). The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental United States generally accepted accounting principles. The Codification did not change United States generally accepted accounting principles but reorganizes the literature. All other accounting literature not included in the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009 and is effective for interim and annual periods ending after September 15, 2009. Subsequent changes to the Codification will be released through Accounting Standards Updates ( ASU ), which serve to update the Codification, provide background information about the guidance and provide the basis for conclusions on the changes in the Codification. The Company has conformed its financial statements and related notes to the new Codification for the three and nine months ended September 30, 2009.

In conjunction with the issuance of SFAS No. 168, the FASB issued ASU No. 2009-01 Topic 105, *Generally Accepted Accounting Principles* ( ASC No. 2009-01 ). ASU No. 2009-01 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with United States generally accepted accounting principles. ASU No. 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of this ASU did not have a material impact on the Company's financial position or results of operation as of and for the three and nine months ended September 30, 2009.

***Fair Value Measurements and Other-Than-Temporary Impairments***

In April 2009, the FASB issued three Staff Positions ( FSP ): (1) ASC 320-10, *Investments - Debt and Equity Securities* (includes former FSP No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*). The ASC changes existing guidance for determining whether impairment of debt securities is other-than-temporary; (2) ASC 820-10, *Fair Value Measurements and Disclosures* (includes former FSP No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). This ASC, while emphasizing that the objective of fair value measurement described in ASC 820 (formerly SFAS No. 157, *Fair Value Measurements*) remains unchanged, provides additional guidance for determining whether market activity for a financial asset or liability has significantly decreased, as well as for identifying circumstances that indicate that transactions are not orderly; and (3) ASC 825-10, *Financial Instruments* (includes former FSP No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*). This ASC requires disclosures about fair values of financial instruments in all interim financial statements, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. These ASCs were effective for interim and annual periods ending after June 15, 2009. The Company adopted the ASCs effective January 1, 2009, and the adoption of did not have a material impact on the Company's condensed consolidated financial statements as of September 30, 2009.

***Business Combinations***

In April 2009, the FASB issued ASC 805-10, *Business Combinations* (includes former FSP No. FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*). This ASC amends and clarifies the provisions of ASC 805, formerly SFAS No. 141(R), *Business Combinations*, with respect to the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies associated with a business combination. The provisions of the ASC are effective, for the Company, for business combinations occurring after January 1, 2009. The adoption of the ASC did not have a material impact on the Company's condensed consolidated financial statements as of September 30, 2009.





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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**4. Recent Accounting Pronouncements (Continued)**

***Subsequent Events***

In May 2009, the FASB issued ASC 855, *Subsequent Events* (formerly SFAS No. 165, *Subsequent Events*), which provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. This ASC distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. Furthermore, ASC 855 requires disclosure of the date through which subsequent events were evaluated. ASC 855 is effective for interim and annual periods ending after June 15, 2009. The Company has adopted ASC 855, and has evaluated subsequent events through November 13, 2009.

**5. 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, 2009 and 2008, respectively, all potentially dilutive shares were anti-dilutive and therefore excluded from the computation of diluted net income (loss) per share. The anti-dilutive common shares totaled 4,000,281 shares and 633,823 shares for the three months ended September 30, 2009 and 2008, respectively, and 2,526,183 shares and 465,482 shares for the nine months ended September 30, 2009 and 2008, respectively.

**6. Discontinued operations**

On October 31, 2008, the Company discontinued its Ossatron® mobile service business. The Company sold certain assets for a total cash consideration of \$400,000 to a minority shareholder of the Company and recorded a gain of approximately \$106,000.

On June 3, 2009, the Company sold its veterinary business to Pulse Veterinary Technologies, LLC ( Pulse Vet ) for a total cash consideration of \$3,500,000. As a result of the sale, the Company recorded a gain of approximately \$2,489,028.

Accordingly, the Company's condensed consolidated financial statements have been prepared with the net assets, results of operations, and cash flows of these businesses displayed separately as discontinued operations.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**6. Discontinued operations (continued)**

The operating results of the discontinued operations are summarized as follows:

	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Revenue	\$	\$ 1,568,577	\$ 1,458,107	\$ 4,618,077
Cost of revenues		136,075	372,547	795,079
Gross profit		1,432,502	1,085,560	3,822,998
Operating expenses				
Depreciation expense		289,134	2,917	961,765
Other operating expenses		541,560	503,873	2,107,760
Total operating expenses		830,694	506,790	3,069,525
Operating income		601,808	578,770	753,473
Other income (expense)		(36,274)	2,536	(68,811)
Income from discontinued operations before income taxes		565,534	581,306	684,662
Income tax expense				
Net income from discontinued operations, net of income tax	\$	\$ 565,534	\$ 581,306	\$ 684,662

The Company's assets and liabilities related to discontinued operations were as follows:

	September 30, 2009	December 31, 2008
Cash	\$	\$ 127,001
Accounts receivable - trade, net		581,200
Inventory	168,509	558,543
Prepaid expenses and other assets		18,273
Total current assets	168,509	1,285,017
Property and equipment, net	924,971	1,011,734

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Total assets	1,093,480	2,296,751
Accounts payable and accrued expenses	(655,761)	(845,593)
Net assets of discontinued operations	\$ 437,719	\$ 1,451,158

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**7. Inventory**

Inventory consists of the following:

	September 30, 2009	December 31, 2008
Continuing Operations		
Inventory finished goods	\$ 469,082	\$ 448,279
Inventory parts	115,490	236,471
 Total Inventory	 \$ 584,572	 \$ 684,750

	September 30, 2009	December 31, 2008
Discontinued Operations		
Inventory finished goods	\$	\$ 258,035
Inventory parts	168,509	300,508
 Total Inventory	 \$ 168,509	 \$ 558,543

**8. Property and equipment**

Property and equipment consists of the following:

	September 30, 2009	December 31, 2008
Cost		
Machines and equipment	\$ 199,520	\$ 204,711
Office and computer equipment	308,977	353,098
Leasehold improvements	67,421	91,590
Furniture and fixtures	27,427	34,915
Software	40,232	40,233
Other assets	4,575	21,688
 Total	 648,152	 746,235
Accumulated depreciation	(511,261)	(466,444)
 Net property and equipment	 \$ 136,891	 \$ 279,791

The aggregate depreciation charged to operations was \$46,636 and \$70,031 for the three months ended September 30, 2009 and 2008, respectively, and \$150,482 and \$193,602 for the nine months ended September 30, 2009 and 2008, respectively.



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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**8. Property and equipment (continued)**

Property and equipment related to discontinued operations (Note 6) consists of the following:

	September 30, 2009	December 31, 2008
Cost		
OssaTron devices	\$ 4,837,165	\$ 4,837,165
Vehicles and equipment	38,897	376,511
Furniture and fixtures		9,765
Software		4,238
Office and computer equipment		1,941
Other assets		8,520
 Total	 4,876,062	 5,238,140
Accumulated depreciation	(3,951,091)	(4,226,406)
 Net property and equipment	 \$ 924,971	 \$ 1,011,734

The aggregate depreciation charged to discontinued operations was \$0 and \$289,134 for the three months ended September 30, 2009 and 2008, respectively, and \$2,917 and \$961,765 for the nine months ended September 30, 2009 and 2008, respectively.

**9. Intangible assets**

Intangible assets consist of the following:

	September 30, 2009	December 31, 2008
Cost		
Patents, at cost	\$ 3,502,135	\$ 3,502,135
Less accumulated amortization	(1,278,151)	(1,048,084)
 Net intangible assets	 \$ 2,223,984	 \$ 2,454,051

The aggregate amortization charged to amortization expense was \$76,689 and \$76,689 for the three months ended September 30, 2009 and 2008, respectively, and \$230,067 and \$230,067 for the nine months ended September 30, 2009 and 2008, respectively.

**10. Income taxes**

Deferred income taxes are provided for temporary differences between the carrying amounts and tax bases of assets and liabilities. Deferred taxes are classified as current or noncurrent based on the financial statement classification of the related asset or liability giving rise to the temporary difference. For those deferred tax assets or liabilities (such as the tax effect of the net operating loss carryforward) which do not relate to a financial statement asset or liability, the classification is based on the expected reversal date of the temporary difference.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**11. Notes payable, related parties**

The notes payable, related parties consist of the following:

	September 30, 2009	December 31, 2008
Notes payable, unsecured, bearing interest at 6% to HealthTronics, Inc. a shareholder of the Company. The notes were issued in conjunction with the Company's purchase of the orthopedic division of HealthTronics, Inc. on August 1, 2005. Quarterly interest through June 30, 2010 is 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 totaled \$1,136,981 and \$911,564 at September 30, 2009 and December 31, 2008, respectively.	\$ 5,136,981	\$ 4,911,564
Notes payable, unsecured, bearing interest at 15% to Prides Capital Fund I, LP and NightWatch Capital Partners II, LP, shareholders of the Company. Quarterly interest through September 30, 2009 is accrued and added to the principal balance. Interest is paid quarterly in arrears beginning December 31, 2008, if elected by the holder. As of September 30, 2009, the holder has not elected to have interest paid. All remaining unpaid accrued interest and principal is due September 30, 2011. Accrued interest totaled \$322,573 and \$20,251 at September 30, 2009 and December 31, 2008, respectively. All or any portion of the unpaid principal can be converted into common stock with a conversion price of \$2.92 per share.	3,522,573	1,095,251
Total	8,659,554	6,006,815
Less current portion		
Non current portion	\$ 8,659,554	\$ 6,006,815

Interest expense on notes payable, related parties totaled \$197,097 and \$72,608 for the three months ended September 30, 2009 and 2008, respectively, and \$527,739 and \$213,051 for the nine months ended September 30, 2009 and 2008, respectively.

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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**12. Commitments and Contingencies**

The Company leases office and warehouse space. Rent expense was \$137,362 and \$151,527 for the three months ended September 30, 2009 and 2008, respectively, and \$433,296 and \$466,967 for the nine months ended September 30, 2009 and 2008, respectively.

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 consolidated financial position or results of operations of the Company.

**13. 401k plan**

The Company sponsors a 401k plan that covers all employees who meet the eligibility requirements. The Company matches 50% of employee contributions up to 6% of their compensation. The Company contributed \$12,330 and \$19,695 to the plan for the three months ended September 30, 2009 and 2008, respectively, and \$39,378 and \$52,910 for the nine months ended September 30, 2009 and 2008, respectively.

**14. Going concern**

As shown in the accompanying consolidated financial statements, the Company incurred a net loss of \$3,450,462 and \$7,823,755 for the nine months ended September 30, 2009 and 2008, respectively. The Company incurred a net loss from continuing operations of \$6,520,796 and \$8,508,417 for the nine months ended September 30, 2009 and 2008, respectively. These operating losses create an uncertainty about the Company's ability to continue as a going concern. Management of the Company believes potential additional investors, outstanding warrant exercise or other potential financing will provide the necessary funding for the Company. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. The Company is economically dependent upon future financing to fund ongoing operations. During the nine months ended September 30, 2009, the Company obtained cash infusions totaling \$2,125,000 in the form of notes payable, related parties (Note 11). The notes payable can be converted into additional shares of common stock with all or any portion of the unpaid principal at a conversion price of \$2.92 per share. On June 3, 2009 the Company sold its veterinary business for a total cash consideration of \$3,500,000 (Note 6). Additionally, in September 2009, prior to the Merger (Note 3), SANUWAVE sold units to a group of accredited investors for \$1,819,844. On a post Merger basis, the unit consisted of one share of the Company's common stock, one warrant to purchase an additional share of the Company for \$4.00 per share and one warrant to purchase an additional share of the Company for \$8.00 per share.



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**SANUWAVE HEALTH, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**September 30, 2009**

**15. Stock-based compensation**

During 2006, SANUWAVE approved the 2006 Stock Incentive Plan ( the Plan ) and certain Nonstatutory Stock Option Agreements with key employees. The Nonstatutory Stock Option Agreements have terms substantially the same as the Plan. The Plan permits granting of awards to selected employees and directors of the Company in the form of options to purchase shares of common stock. Options granted may include Nonstatutory Options as well as Non-qualified Incentive Stock Options. The Plan is currently administered by the board of directors of SANUWAVE. The Plan gives broad powers to the board of directors of SANUWAVE to administer and interpret the particular form and conditions of each option. The stock options granted were nonstatutory options which, under the Plan, vest equally over a four year period, and have a 10-year term. The options were granted to employees at an exercise price of \$2.92 per share, which was deemed to be the fair market value of the common stock on the date of the grant. It is the Company's policy to issue new stock certificates to satisfy stock option exercises. The Company intends to adopt and assume the Plan. For the three months ended September 30, 2009, the Company awarded 403,030 shares of restricted stock to certain members of management. The restrictions on the stock will lapse at 25% per year from the employees first date of service with the Company after the lock-up agreement expires on January 1, 2011 subject to other restrictions on the stock as more detailed in the restricted stock agreements.

For the three months ended September 30, 2009, the Company granted 163,745 options to employees at an exercise price of \$2.92 per share.

In addition, for the three months ended September 30, 2009, the Company granted the following supplemental options: 40,637 supplement options at an exercise price of \$5.25 per share which vest at the earlier of six years from the employee's first date of service or the date on which the closing price of the Company's stock exceeds \$15.75 per share; 40,637 supplement options at an exercise price of \$5.25 per share which vest at the earlier of six years from the employee's first date of service or the first date on which the closing price of the Company's stock exceeds \$31.50 per share; and, 60,958 supplement options at an exercise price of \$5.25 per share which vest at the earlier of six years from the employee's first date of service or the date on which the closing price of the Company's stock exceeds \$47.25 per share.

Using the Black-Scholes option pricing model, management has determined that the options had a weighted average fair value per share of \$1.48 at September 30, 2009 and \$1.42 at December 31, 2008. Compensation cost will be recognized over the applicable service period. For the three months ended September 30, 2009 and 2008, the Company recognized \$318,008 and \$133,696 as compensation cost, respectively, and \$585,400 and \$401,088 for the nine months ended September 30, 2009 and 2008, respectively.

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**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, 2008 included in our Current Report on Form 8-K filed with the Securities and Exchange Commission ( SEC ) on September 30, 2009.*

**Overview**

We are an emerging medical technology company focused on the development and commercialization of noninvasive, biological response activating devices in the regenerative medicine area for the repair and regeneration of tissue, musculoskeletal and vascular structures. Our portfolio of products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions.

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

With the divestiture of our worldwide Versatron® veterinary product line in June 2009, we are now entirely focused on developing our PACE technology to stimulate healing in:

- wound conditions, including diabetic foot ulcers, pressure sores, burns and other skin eruption conditions; orthopedic/spine applications, such as speeding the healing of fractures (including non-union or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, eliminating chronic pain in joints from trauma or arthritis, 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 structures for removing plaque due to atherosclerosis and improving heart muscle performance.

**Recent Developments**

On September 25, 2009, SANUWAVE Health (formerly named Rub Music Enterprises, Inc.) and RME Delaware Merger Sub, Inc., a Nevada corporation and wholly-owned subsidiary of SANUWAVE Health (the Merger Sub), entered into a reverse merger agreement (the Merger Agreement) with SANUWAVE. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, with SANUWAVE as the surviving entity (the Merger). See further discussion in Note 3 to the Condensed Consolidated Financial Statements.

We are enrolling patients for our IDE wound care clinical study focused on the healing of diabetic foot ulcers utilizing our lead product candidate, dermaPACE. We believe our experience from preclinical research and the clinical use of our predecessor devices in Europe and Asia, as well as our Ossatron® device in the United States for the last nine years, demonstrate the safety, clinical utility and efficacy of our product candidates. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications, as well as toward the development of next generation devices utilizing our PACE technology to maximize healing response and intervention.

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We believe that those studies suggest that our platform technology will be effective in our target applications. If successful, we expect these clinical studies should lead to regulatory approval of our regenerative product candidates in the United States, Europe and Asia. If approved by the appropriate regulatory authorities, we believe that our product candidates will offer new, effective and noninvasive treatment options in wound healing, orthopedic/spine injuries, plastic/cosmetic uses and cardiac procedures to improve the quality of life for millions of patients suffering injuries or deterioration of tissue, bones and vascular structures.

### **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 sale of our veterinary division in June 2009, and product sales. At September 30, 2009, the balance of cash and cash equivalents totaled \$3.3 million.

We continue to incur research and development expenses for clinical trials and the development of products for additional indications. We expect that research and development expenses will continue to increase as a result of new and ongoing clinical and pre-clinical studies in the United States and in Europe, as well as expenses associated with regulatory filings. In addition, we anticipate that our general and administrative expenses will continue to increase as we expand our operations, facilities and other administrative activities related to our efforts to bring our product candidates to commercialization.

Since our inception, we have incurred losses from operations each year. As of September 30, 2009, we had an accumulated deficit of \$36.0 million. 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 few years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products. In addition, given the sale of our veterinary division in 2009 and the discontinuation of the Ossatron® mobile service business in 2008, we are not actively commercializing any products in the United States.

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 marketing, sales and distribution;
- the cost and timing associated with establishing reimbursement for our products;
- the timing and results of our pre-clinical research programs;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior as businesses and individuals suffer from the current economic downturn.

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 Risk Factors.

### **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.

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On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses, fair valuation of inventory, fair valuation of stock related to stock-based compensation and income taxes. 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 discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any other future period.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements filed with our Current Report on Form 8-K filed on September 30, 2009, we believe that the following accounting policies relating to revenue recognition, research and development costs, inventory valuation, stock-based compensation and income taxes are significant and, therefore, 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. Fees from services performed are recognized when the procedure 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, product related consultants, contract manufacturer start-up costs 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, and consists primarily of the purchase of component materials for assembly of finished products, less reserves for obsolescence.

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

During 2006, SANUWAVE's board of directors approved the adoption of the 2006 Stock Incentive Plan (the Plan). The Plan provides that stock options, other equity interests or equity-based incentives in SANUWAVE may be granted to key personnel at an exercise price determined by SANUWAVE's board of directors, at the time the option is granted, taking into account the fair value of the common stock on the date of grant. The maximum term of any option granted pursuant to the Plan is ten years from the date of grant.

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In accordance with ASC 718, *Compensation – Stock Compensation* (formerly included in SFAS No. 123(R), *Share-Based Payment*), 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 amortized to expense over the options' vesting periods for the nine months ended September 30, 2009 and the year ended December 31, 2008, respectively: risk-free interest rate of 2.41% to 3.07% and 3.29%, expected dividend yield of 0% and 0%, volatility factor of the expected market price of our common stock of 65.0% and 46.3%, and weighted average expected life of the option of 6.0 and 6.0 years. 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. The risk-free rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of the grant.

***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). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases 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 related to future years, including loss carryforwards, if there is not sufficient evidence to indicate that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in future years.

**Results of Operations for the Three Months ended September 30, 2009 and 2008 (Unaudited)*****Disposal of Veterinary Division***

On June 3, 2009, we sold our veterinary division for \$3.5 million in cash to Pulse Vet. As a result, we recorded a net gain of \$2.5 million on the transaction. Under terms of the sale agreement, we will continue to provide purchasing, production, shipping and warehousing services to Pulse Vet for a fee until April 30, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. The revenue for these transitional services is included in other income (expense). The income from discontinued operations was \$0 for the three months ended September 30, 2009, as compared to \$0.6 million for the same period in 2008.

***Revenues and Cost of Revenues***

Revenues for the three months ended September 30, 2009 were \$134,771, compared to \$167,423 for the same period in 2008, a decrease of 20%. These revenues result primarily from sales of devices and applicators in Europe of our legacy Evotron® device for orthopedic conditions and our dermaPACE® device for advanced wound care and decreased for the three months ended September 30, 2009 compared to 2008 primarily because of declining sales of the legacy Evotron® device due to our focus on our resources in the United States and the reduction of our European sales and marketing staff.

Cost of revenues for the three months ended September 30, 2009 was \$30,753, compared to \$60,213 for the same period in 2008. Gross profit as a percentage of revenues was 77% for the three months ended September 30, 2009, as compared to 64% for the same period in 2008. The increase in gross profit in 2009 was primarily due to increasing sales of the higher margin dermaPACE® device applicator kits as a percentage of sales.

***Research and Development Expenses***

Research and development expenses for the three months ended September 30, 2009 were \$1.1 million, compared to \$0.9 million for the same period in 2008, an increase of 23%. 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, product related consultants, contract manufacturer start-up costs 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. Research and development costs increased in 2009 as compared to the same period in 2008 due to higher costs of the ongoing clinical trial of dermaPACE® for diabetic foot ulcers in the United States as the enrollment has increased during 2009.



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We expect that research and development expenses will continue to increase as a result of next generation technology development, the ongoing clinical trial of dermaPACE for diabetic foot ulcers in the United States and other new product candidates, as well as continuing expenses associated with pre-clinical studies and regulatory filings.

### *General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2009 were \$1.5 million, compared to \$1.9 million for the same period in 2008, a decrease of 21%. We closed our European office, effective April 2009. Expenses related to this office totaled \$0.1 million for the three months ended September 30, 2009, compared to \$0.7 million for the same period in 2008. Excluding these costs, general and administrative expenses were \$1.4 million for the three months ended September 30, 2009, as compared to \$1.2 million for the same period in 2008, an increase of 17%.

General and administrative expenses include the non-cash compensation costs for stock compensation of \$0.3 million for the three months ended September 30, 2009, compared to \$0.1 million for the same period in 2008, due to new grants of options and restricted stock to management and directors of the Company in the three months ended September 30, 2009. In addition, for the three months ended September 30, 2009 the Company recorded legal, accounting and related expenses of \$0.3 million in regard to the Merger. Excluding these costs and the costs related to the European office, general and administrative expenses were \$0.8 million for the three months ended September 30, 2009, as compared to \$1.1 million for the same period in 2008, a decrease of 27%. The decrease is primarily due to reduced headcount and the related savings in wages, bonuses and benefit related expenses.

We expect that general and administrative expenses will increase as we expand our operations and other administrative activities related to our efforts to bring our products to commercialization.

### *Depreciation and Amortization*

Depreciation and amortization for the three months ended September 30, 2009 was \$0.1 million, compared to \$0.1 million for the same period in 2008.

### *Other Income (Expense)*

On June 3, 2009, we sold our veterinary division to Pulse Vet. Under terms of the sale agreement, we will continue to provide purchasing, production, shipping and warehousing services to Pulse Vet for a fee until April 30, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. The revenue for these transitional services was \$0.1 million for the three months ended September 30, 2009.

Interest expense due to related parties for the three months ended September 30, 2009 was \$0.2 million, compared to \$0.1 million for the same period in 2008. The increase was due to interest on notes payable to related parties issued to Prides Capital Fund I, L.P., totaling \$3.1 million, entered into between October 2008 and May 2009, and one note payable to related parties, issued to NightWatch Capital Partners II, L.P., for \$0.1 million, entered into in October 2008. The notes payable to related parties bear interest at 15% annually. Interest is paid quarterly in arrears, if elected by the holders of the notes payable. As of September 30, 2009, the holders of the notes payable had not elected to receive interest quarterly. All remaining unpaid accrued interest and principal is due September 30, 2011.

### *Provision for Income Taxes*

At September 30, 2009, we had Federal net operating loss carryforwards of approximately \$27.9 million 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.

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*Net Income (Loss)*

Net loss for the three months ended September 30, 2009 was \$2.7 million, or \$(0.23) per basic and diluted share, compared to net loss of \$2.4 million, or \$(0.21) per basic and diluted share, for the three months ended September 30, 2008. This included a loss from continuing operations of \$2.7 million, or \$(0.23) per basic and diluted share, for the three months ended September 30, 2009, compared to a loss from continuing operations of \$2.9 million, or \$(0.26) per basic and diluted share, for the three months ended September 30, 2008. We anticipate that our operating losses will continue over the next few years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products.

**Results of Operations for the Nine Months ended September 30, 2009 and 2008 (Unaudited)**

*Disposal of Veterinary Division*

On June 3, 2009, we sold our veterinary division for \$3.5 million in cash to Pulse Vet. As a result, we recorded a net gain of \$2.5 million on the transaction. Under terms of the sale agreement, we will continue to provide purchasing, production, shipping and warehousing services to Pulse Vet for a fee until April 30, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. The net income from discontinued operations was \$0.6 million for the nine months ended September 30, 2009, as compared to \$0.7 million for the same period in 2008.

*Revenues and Cost of Revenues*

Revenues for the nine months ended September 30, 2009 were \$0.5 million, compared to \$0.9 million for the same period in 2008, a decrease of 38%. These revenues result primarily from sales of devices and applicators in Europe of our legacy Evotron® device for orthopedic conditions and our dermaPACE device for advanced wound care and decreased for the nine months ended September 30, 2009 compared to 2008 primarily because of declining sales of the legacy Evotron® device due to our focus on our resources in the United States and the reduction of our European sales and marketing staff.

Cost of revenues for the nine months ended September 30, 2009 was \$0.1 million, compared to \$0.3 million for the same period in 2008. Gross profit as a percentage of revenues was 76% for the nine months ended September 30, 2009, as compared to 67% for the same period in 2008. The increase in gross profit in 2009 was primarily due to increasing sales of the higher margin dermaPACE device applicator kits as a percentage of sales.

*Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2009 were \$2.7 million, compared to \$2.4 million for the same period in 2008, an increase of 12%. 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, product related consultants, contract manufacturer start-up costs 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. Research and development costs increased in 2009 as compared to the same period in 2008 due to higher costs of the ongoing clinical trial of dermaPACE for diabetic foot ulcers in the United States as the enrollment has increased during 2009.

We expect that research and development expenses will continue to increase as a result of next generation technology development, the ongoing clinical trial of dermaPACE for diabetic foot ulcers in the United States and other new product candidates, as well as continuing expenses associated with pre-clinical studies and regulatory filings.



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### *General and Administrative Expenses*

General and administrative expenses for the nine months ended September 30, 2009 were \$3.4 million, compared to \$6.0 million for the same period in 2008, a decrease of 43%. We closed our European office, effective April 2009. Expenses related to this office totaled \$0.8 million for the nine months ended September 30, 2009, as compared to \$2.1 million for the same period in 2008. Excluding these costs, general and administrative expenses were \$2.6 million for the nine months ended September 30, 2009, as compared to \$3.9 million for the same period in 2008, a decrease of 33%.

General and administrative expenses include the non-cash compensation costs for stock compensation of \$0.6 million for the nine months ended September 30, 2009, compared to \$0.4 million for the same period in 2008, due to new grants of options and restricted stock to management and directors of the Company in the three months ended September 30, 2009. In addition, for the nine months ended September 30, 2009 the Company recorded legal, accounting and related expenses of \$0.3 million in regard to the Merger. Excluding these costs and the costs related to the European office, general and administrative expenses were \$1.7 million for the nine months ended September 30, 2009, compared to \$3.5 million for the same period in 2008, a decrease of 51%. The decrease is primarily due to reduced headcount and the related savings in wages, bonuses and benefits, and reduced legal expenses. We expect that general and administrative expenses will increase as we expand our operations and other administrative activities related to our efforts to bring our products to commercialization.

### *Depreciation and Amortization*

Depreciation and amortization for the nine months ended September 30, 2009 was \$0.4 million, compared to \$0.4 million for the same period in 2008.

### *Other Income (Expense)*

On June 3, 2009, we sold our veterinary division to Pulse Vet. Under terms of the sale agreement, we will continue to provide purchasing, production, shipping and warehousing services to Pulse Vet for a fee until April 30, 2011, unless Pulse Vet elects to terminate the agreement at an earlier date. The revenue for these transitional services was \$0.1 million for the nine months ended September 30, 2009.

Interest expense due to related parties for the nine months ended September 30, 2009 was \$0.5 million, compared to \$0.2 million for the same period in 2008. The increase was due to interest on notes payable to related parties issued to Prides Capital Fund I, L.P., totaling \$3.1 million, entered into between October 2008 and May 2009, and one note payable to related parties, issued to NightWatch Capital Partners II, L.P., for \$0.1 million, entered into in October 2008. The notes payable to related parties bear interest at 15% annually. Interest is paid quarterly in arrears, if elected by the holders of the notes payable. As of September 30, 2009, the holders of the notes payable had not elected to receive interest quarterly. All remaining unpaid accrued interest and principal is due September 30, 2011.

### *Provision for Income Taxes*

At September 30, 2009, we had Federal net operating loss carryforwards of approximately \$27.9 million 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.

### *Net Income (Loss)*

Net loss for the nine months ended September 30, 2009 was \$3.5 million, or \$(0.30) per basic and diluted share, compared to net loss of \$7.8 million, or \$(0.73) per basic and diluted share, for the nine months ended September 30, 2008. This included a loss from continuing operations of \$6.5 million or \$(0.56) per basic and diluted share, for the nine months ended September 30, 2009, compared to a loss from continuing operations of \$8.5 million, or \$(0.79) per basic and diluted share, for the nine months ended September 30, 2008. We anticipate that our operating losses will continue over the next few years as we continue to fund our research and development activities and clinical trials, and as we prepare for a future sales network to represent our products.



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**Liquidity and Capital Resources**

We incurred a net loss of \$2.7 million and \$3.5 million for the three and nine months ended September 30, 2009, respectively, which includes a loss from continuing operations of \$2.7 million and \$6.5 million for the three and nine months ended September 30, 2009, respectively. We incurred a net loss of \$9.4 million and \$12.1 million for the years ended December 31, 2008 and 2007, respectively. These operating losses create an uncertainty about our ability to continue as a going concern. Management believes we will raise additional capital through public or private equity offerings, outstanding warrant exercise or other potential financing sources. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. We are economically dependent upon future capital contributions or financing to fund ongoing operations. On June 3, 2009, we sold our veterinary division for \$3.5 million in cash to Pulse Vet. During the nine months ended September 30, 2009 and the year ended December 31, 2008, we obtained cash infusions totaling \$2.1 million and \$1.1 million, respectively, in the form of notes payable from related parties. The notes payable can be converted into additional shares of common stock, with all or any portion of the unpaid principal, at a conversion price of \$2.92 per share. In addition, for the nine months ended September 30, 2009 and the year ended December 31, 2008, additional shares of stock were issued to stockholders for total cash proceeds of \$1.8 million and \$5.7 million, respectively.

At September 30, 2009, we had \$3.3 million in cash and cash equivalents held in four financial institutions. Our excess cash reserves are invested in money market accounts. We believe that the September 30, 2009 balance of our cash and cash equivalents will be sufficient to fund our business operations through the first quarter of 2010.

We expect to devote substantial resources to continue our research and development efforts, including clinical trials. Clinical study costs are comprised of payments for work performed by contract research organizations, universities and hospitals. Because of the significant time it will take for our products to complete the clinical trial process, and for us to obtain approval from regulatory authorities and successfully commercialize our products, we will require substantial additional capital resources. We may raise additional capital through public or private equity offerings, outstanding warrant exercise, debt financings, corporate collaborations or other means. We may attempt to raise additional capital due to 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 stockholders 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. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our research, pre-clinical or clinical programs.

For the nine months ended September 30, 2009, net cash used by continuing operations for operating activities was \$5.2 million, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by continuing operations for financing activities for the nine months ended September 30, 2009 was \$3.7 million, which consisted primarily of the proceeds from issuance of notes payable to related parties of \$2.1 million and the sale of common stock to accredited investors of \$1.8 million offset the by the repurchase of common stock prior to the Reverse Merger of \$0.2 million. Net cash provided by discontinued operations was \$4.3 million for the nine months ended September 30, 2009, which primarily includes \$0.7 million for discontinued operating activities and \$3.6 million for the sale of our veterinary division.

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For the nine months ended September 30, 2008, net cash used by continuing operations for operating activities was \$7.7 million, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash used by continuing operations for investing activities was \$0.1 million for the nine months ended September 30, 2008 and included purchases of property and equipment for research and development. Net cash provided by continuing operations for financing activities for the nine months ended September 30, 2008 was \$5.7 million, primarily consisting of net proceeds from issuance of capital stock to related parties. Net cash provided by discontinued operations was \$2.2 million for the nine months ended September 30, 2008.

### **Segment 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/spine, plastic/cosmetic and cardiac conditions.

### **Comprehensive Loss**

FASB ASC 220, *Comprehensive Income* (formerly SFAS No. 130), establishes standards for reporting and display of comprehensive income (loss) and its components in the condensed consolidated financial statements. Our comprehensive loss as defined by ASC 220 is the total of net loss and all other changes in equity resulting from non-owner sources, including unrealized gains/losses on foreign currency translation adjustments.

### **Contractual Obligations**

Our major outstanding contractual obligations relate to our operating leases for our facilities, purchase and supplier obligations for raw materials and equipment, and our notes payable.

In October 2006, we entered into a sublease agreement for the corporate office in Alpharetta, Georgia for 15,025 square feet of space. Under the terms of the sublease, we pay monthly rent of \$18,468, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the sublease continued until September 30, 2009, and we have exercised the option to extend the term to October 31, 2012.

In April 2007, we entered into a lease agreement for the production and research and development office for 5,168 square feet of space. Under the terms of the lease, we pay monthly rent of \$8,075, as adjusted on an annual basis for additional proportionate operating and insurance costs associated with the building over the base amount. The initial term of the sublease continues until July 31, 2010, and the lease provides for an annual increase in the base rent of three percent per year.

We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantities of raw materials for our products through the development, clinical testing and commercialization phases. We have contractual obligations under a supply agreement with SwissTronics Contract Manufacturing AG for the manufacture of our devices.

In August 2005, as part of the purchase of the orthopedic division assets of HealthTronics, Inc., we entered into two promissory notes with HealthTronics, Inc. for \$2.0 million each. The promissory notes bear interest at 6% annually. Quarterly interest through June 30, 2010 is 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 on the promissory notes totaled \$1.1 million at September 30, 2009 and \$0.9 million at December 31, 2008.

In the fourth quarter of 2008, we entered into three notes payable with Prides Capital Fund I, L.P. for \$1.0 million in total and one note payable with NightWatch Capital Partners II, L.P. for \$0.1 million. The notes payable bear interest at 15% annually. Interest is paid quarterly in arrears beginning December 31, 2008, if elected by the holders of the notes payable. As of September 30, 2009, the holders of the notes payable had not elected to receive interest quarterly. All remaining unpaid accrued interest and principal is due September 30, 2011. All or any portion of the unpaid principal can be converted into common stock with a conversion price of \$2.92 per share. Accrued interest on the notes payable totaled \$0.3 million at September 30, 2009 and \$20,251 at December 31, 2008.



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**Off-Balance Sheet Arrangements**

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

**Effects of Inflation**

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

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

Not applicable.

**Item 4. CONTROLS AND PROCEDURES**

Not applicable.

**Item 4T. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

The Company has established disclosure controls and procedures to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known on a timely basis to the officers who certify its financial reports and to other members of senior management and the Company's board of directors. Based on their evaluation as of September 30, 2009, the principal executive officer and the principal financial officer of the Company have concluded that the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

**Changes in Internal Controls Over Financial Reporting**

There were no changes in internal controls over financial reporting that occurred during the three months ended September 30, 2009 that have materially affected, or are reasonably likely to materially impact, our internal controls over financial reporting.

**PART II OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

Other than legal proceedings relating to our intellectual property, there are no material pending legal proceedings to which we are a party or of which any of our properties are subject; nor are there material proceedings known to us to be contemplated by any governmental authority. We have several material pending legal proceedings relating to our patents. For information regarding these legal proceedings, please see the Intellectual Property Patents section of our Current Report on Form 8-K filed with the SEC on September 30, 2009, which section is hereby incorporated by reference herein. There are no material proceedings known to us, pending or contemplated, in which any of our directors, officers or affiliates or any of our principal security holders, or any associate of any of the foregoing, is a party or has an interest adverse to us.

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**Item 1A. RISK FACTORS**

**Risks Related to Our Business**

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

We have invested and continue to invest a significant portion of our time and resources in developing and testing our PACE product candidates, with current emphasis on dermaPACE. As a result of our significant research, clinical development, regulatory compliance and general and administrative expenses, we expect to incur losses for at least the next several years as we continue to incur significant expenses for clinical trials. As of September 30, 2009, we had an accumulated deficit of \$36.0 million. In June 2009, we sold our Versatron® veterinary product line. This transaction enabled us to focus our expertise and future development efforts on the development of our PACE technology in wound care, orthopedic/spine, plastic/cosmetic and cardiac conditions. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenues and we may never achieve or maintain profitability.

***Current economic conditions could adversely affect our operations.***

According to the National Bureau of Economic Research, the United States economy has been in a recession since December 2007. This economic downturn and the instability of markets have made the business climate more volatile and more costly. Consequently, our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. While we believe that our existing cash and investments will be sufficient to meet our anticipated cash requirements at least through the first quarter of 2010, a more radical economic downturn or increase in our expenses will likely make it more difficult for us to seek additional financing, and may force us to accept less than attractive rates or terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business strategy, financial performance and stock price, and could require us to delay or abandon product development plans or plans to acquire additional technology.

There is a risk that one or more suppliers, clinical investigators, consultants and other partners may encounter difficulties during these challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

The current economic conditions may also adversely affect our potential customers, including patients, medical professionals and their practices, hospitals and other healthcare providers. These conditions may also impact the overall amount spent on healthcare generally. This could result in a decrease in the demand for our products, longer sales cycles, slower adoption of our new technology and increased price competition.

***Our product candidates may not be developed or commercialized successfully.***

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

We are subject to the risks that:

- the FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates.

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

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;

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the inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our trials; and  
regulatory delays or other regulatory actions.

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

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

Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products. We face competition from established medical device, pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies, and private and public research institutions in the United States and abroad. Many of our principal competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or mergers with or acquisitions by, large and established companies or through the development of novel products and technologies.

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

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

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

***We currently purchase most of our raw materials from single suppliers. If we are unable to obtain raw materials and other products from our suppliers that we depend on for our operations, our ability to deliver our products to market will likely be impeded.***

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

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





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### ***The loss of our key management and scientific personnel would likely hinder our ability to execute our business plan.***

As a small company with 23 employees, our success depends on the continuing contributions of our management team and scientific personnel, and on maintaining relationships with the network of medical and academic centers that conduct our clinical trials. We depend on the services of our key scientific employees and principal members of our management team. Our success depends in large part on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical, biotechnology and medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

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

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

### **Risks Related to Intellectual Property**

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

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

- obtain and/or maintain protection for our product candidates under the patent laws of the United States and other countries;
- defend and enforce our patents once obtained;
- obtain and/or maintain appropriate licenses to patents, patent applications or other proprietary rights held by others with respect to our technology, both in the United States and other countries;
- maintain trade secrets and other intellectual property rights relating to our product candidates; and
- operate without infringing upon the patents, trademarks, copyrights and proprietary rights of third parties.

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



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

In particular, we cannot assure you that:

- we or the owners or other inventors of the patents that we own or that have been licensed to us, or that may be issued or licensed to us in the future, were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our patent applications will result in issued patents;
- the patents and the patent applications that we own or that have been licensed to us, or that may be issued or licensed to us in the future, will provide a basis for commercially viable products or will provide us with any competitive advantages, or will not be challenged by third parties;
- the patents and the patent applications that have been licensed to us are valid and enforceable;
- we will develop additional proprietary technologies that are patentable;
- we will be successful in enforcing the patents that we own or license and any patents that may be issued or licensed to us in the future against third parties;
- the patents of third parties will not have an adverse effect on our ability to do business; or
- our trade secrets and proprietary rights will remain confidential.

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

market for our product candidates, negatively impact the prices we can charge for our product candidates, and harm our reputation if infringing or competing products are manufactured to inferior standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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### **Regulatory Risks**

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

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

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected. We cannot be sure that the FDA will not select a different center and/or different legal authority for our other product candidates, in which case the path to regulatory approval would be different and could be more lengthy and costly.

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

- testing;
- manufacturing;
- quality control;
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with the use of the products; and
- obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

We are also subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers and contract testing laboratories, and we cannot be sure that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers, contract manufacturers and contract laboratories. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

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

International sales of our products and any of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the United States will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging and labeling requirements, and import restrictions on medical devices. In addition, each country has its own tariff

regulations, duties and tax requirements. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

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

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

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

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

the product candidate's benefits may not outweigh its risks;

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

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

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

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

The availability and levels of reimbursement by governmental and other third party payers affect the market for our approved products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our approved products in the international markets in which those approvals are sought.

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

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

A provision of the Social Security Act, commonly referred to as the Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other Federal healthcare program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states in which our approved products may be sold have adopted laws similar to the Federal

Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by Federal healthcare programs, but instead apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in Federal healthcare programs.

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

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

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

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

the size of the patient population;

the nature of the clinical protocol requirements;

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

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

the proximity of patients to clinical sites; and

the patient eligibility criteria for the study.

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

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

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

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

regulations could be significant.

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### **Risks Related to Our Common Stock**

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

In the past, we have relied on Prides Capital Partners, LLC ( Prides ) and NightWatch Capital LLC ( NightWatch ) for the ongoing financial support necessary to operate our business. Neither Prides nor NightWatch currently provides us with financing or financial support, nor do they currently intend to provide us any additional financing or financial support in the future. To the extent we must obtain financing to support our cash needs, we will be entirely reliant on third parties for financing. We do not have any lines of credit or other financing arrangements in place with banks or other financial institutions. We will require additional financing in the future, and additional financing may not be available at times, in amounts or on terms acceptable to us, or at all, which would have a material adverse effect on our business.

***If we are unable to successfully raise additional capital in the future, our product development could be limited and our long term viability may be threatened; however, if we do raise additional capital, your percentage ownership as a stockholder could decrease and constraints could be placed on the operations of our business.***

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our capital stock, the issuance of notes payable to related parties, the sale of our veterinary division in June 2009 and product sales. We believe our existing cash and investments will be sufficient to meet our anticipated cash requirements through the first quarter of 2010. We will seek to obtain additional funds at any time in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. These financings could result in substantial dilution to the holders of our common stock or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

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

- unforeseen developments during our pre-clinical activities and clinical trials;
- delays in timing of receipt of required regulatory approvals;
- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of any approved product;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using any of our approved products;
- inability to train a sufficient number of physicians to create a demand for any of our approved products;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;

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

unanticipated difficulties in operating in international markets;

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

unforeseen problems in attracting and retaining qualified personnel to market our approved products;

enactment of new legislation or administrative regulations;

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

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

the failure to comply with regulatory guidelines; and

the uncertainty in industry demand and patient wellness behavior as businesses and individuals suffer from the current economic downturn.

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

If adequate financing is not available, we may be required to delay, scale back or eliminate our operations. Consequently, our long-term viability would be threatened.



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

As of September 30, 2009, Prides owned 66.9% of our outstanding common stock and NightWatch owned 17.0% of our outstanding common stock on a fully diluted basis. In addition, certain of our directors were appointed by Prides and NightWatch to serve on our board of directors. For as long as Prides and NightWatch own a majority of our shares of common stock, they will be able to control the election of all of the members of our board of directors and control the vote of stockholders on other matters. For as long as they own a significant percentage of our outstanding stock, even if less than a majority, Prides and NightWatch will be able to control and exercise significant influence over our business affairs, including the strategic direction of our business generally, the incurrence of indebtedness by us, the issuance of any additional equity securities, the repurchase of equity securities and the payment of dividends, and will have the power to determine or significantly influence the outcome of matters submitted to a vote of our stockholders, including mergers, consolidations, sales or dispositions of assets, reductions in share capital, other business combinations and amendments to our articles of incorporation. Prides and NightWatch may take actions with which you or we do not agree, including actions that delay, defer or prevent a change in control of our Company or that could adversely affect the market price of our common stock. In addition, they may take other action that might be favorable to them, but not favorable to us or our other stockholders. Also, if either Prides or NightWatch sells all or a portion of its interest in us, it may cause the value of your investment to decrease.

### ***Our stock price may be volatile.***

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

- changes in our industry;
- our ability to obtain additional financing and, if available, the terms and conditions of the financing;
- additions or departures of key personnel;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- period-to-period fluctuations in our operating results;
- new regulatory requirements and changes in the existing regulatory environment; and
- general economic conditions and other external factors.

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

### ***There is currently no liquid trading market for our common stock and we cannot ensure that one will ever develop or be sustained.***

To date, there has been no liquid trading market for our common stock and we cannot predict how liquid the market for our common stock might become. Our common stock is quoted on the Over-the-Counter Bulletin Board (the OTCBB ), which is an inter-dealer, over-the-counter market that provides significantly less liquidity than the New York Stock Exchange or the NASDAQ Stock Market. The quotation of our common stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market currently exists. The market price for our common stock is subject to volatility and holders of our common stock may be unable to resell their shares at or near their original purchase price, or at any price. In the absence of an active trading market:

investors may have difficulty buying and selling, or obtaining market quotations;

market visibility for our common stock may be limited; and

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

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***If a public market for our common stock develops, trading will be limited under the SEC's penny stock regulations, which will likely adversely affect the liquidity of our common stock.***

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

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

As of November 10, 2009, the closing price of our common stock was \$5.25. If the price of our common stock decreases to below \$5.00, our common stock will once again be considered a penny stock and be subject to the requirements discussed above.

***We have not voluntarily implemented various corporate governance measures, in the absence of which, shareholders may have more limited protections against interested director transactions, conflicts of interest and similar matters.***

Recent Federal legislation, including the Sarbanes-Oxley Act of 2002, has resulted in the adoption of various corporate governance measures designed to promote the integrity of corporate management and the securities markets. Some of these measures have been adopted in response to legal requirements and others have been adopted by companies in response to the requirements of national securities exchanges, such as the New York Stock Exchange and the NASDAQ Stock Market. Among the corporate governance measures that are required under the rules of the national securities exchanges are those that address board of directors' independence, audit committee oversight and the adoption of a code of ethics. While we intend to adopt certain corporate governance measures, such as a code of ethics and an established audit committee, we presently only have one independent director. It is possible that if we were to have more independent directors on our board of directors, shareholders would benefit from somewhat greater assurances that internal corporate decisions were being made by disinterested directors and that policies had been implemented to define responsible conduct. For example, in the absence of a compensation committee comprised of at least a majority of independent directors, decisions concerning matters such as compensation packages to our executive officers may be made by our directors who have an interest in the outcome of the matters being decided. Prospective investors should bear in mind our current lack of both corporate governance measures and a majority of independent directors in formulating their investment decisions.

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

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

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**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

On September 25, 2009, the Company and Merger Sub entered into the Merger Agreement with SANUWAVE. Pursuant to the Merger Agreement, the Merger Sub merged with and into SANUWAVE, with SANUWAVE as the surviving entity. In connection with the Merger, the Company acquired 100% of the outstanding capital stock of SANUWAVE and the stockholders of SANUWAVE received 11,009,657 shares of the Company's common stock, warrants to purchase up to 1,106,627 shares of the Company's common stock at \$4.00 per share, and warrants to purchase up to an additional 1,106,627 shares of the Company's common stock at \$8.00 per share. In connection with the Reverse Merger, the Company also entered into Stock Repurchase Agreements, all dated as of September 25, 2009, with certain stockholders of the Company, pursuant to which the Company purchased from certain stockholders, for an aggregate purchase price of \$180,000, some or all of the Company's common stock held by such stockholders, such that after the repurchases, 1,500,000 shares of the Company's common stock remained outstanding.

For additional information regarding recent sales and the Merger, see Item 1.01 and 2.01 of the Current Report of Form 8-K filed by the Company on September 30, 2009, which information is hereby incorporated by reference herein.

**Item 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**Item 5. OTHER INFORMATION**

None.

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**Item 6. EXHIBITS**

- 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 the 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 (Incorporate by reference to Appendix A to the Definitive Schedule 14D filed with the SEC on October 16, 2009).
- 3.3 Bylaws (Incorporated by reference to the Form 10-SB filed with the SEC on December 18, 2007).
- 4.1 Form of Class A Warrant Agreement. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 4.2 Form of Class B Warrant Agreement. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 4.3 Form of Amended and Restated Class C Warrant Agreement. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 4.4 Form of Amended Senior Note issued by SANUWAVE, Inc. to Prides Capital Fund I, L.P. and NightWatch Capital Partners II, L.P. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 4.5 Form of Promissory Note, dated August 1, 2005, issued by SANUWAVE, Inc. to Healthtronics, Inc. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.1 Form of Stock Repurchase Agreement, dated as of September 25, 2009, by and among Rub Music Enterprises, Inc. and certain stockholders of Rub Music Enterprises, Inc. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.2 Indemnification Agreement, dated September 25, 2009, by and among Rub Music Enterprises, Inc., SANUWAVE, Inc. and David N. Nemelka (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.3 Form of Lock-Up Agreement, dated September 25, 2009, by and between certain stockholders of Rub Music Enterprises, Inc. and Rub Music Enterprises, Inc. (Incorporate by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.4 Form of Lock-Up Agreement, dated September 2009, by and between certain shareholders of SANUWAVE, Inc. and SANUWAVE, Inc. (Incorporated by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.5 Form of Lock-Up Agreement, dated September 2009, by and between certain shareholders of SANUWAVE, Inc. and SANUWAVE, Inc. (Incorporate by reference to the Form 8-K filed with the SEC on September 30, 2009).



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- 10.6 First Amendment to Employment Agreement, dated September 15, 2009, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporate by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.7 Amendment to Nonstatutory Stock Option Award and Nonstatutory Supplemental Agreements, dated September 15, 2009, by and between SANUWAVE, Inc. and Christopher M. Cashman. (Management compensation plan or arrangement) (Incorporate by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.8 Amendment to Nonstatutory Stock Option Award and Nonstatutory Supplemental Agreements, dated September 15, 2009, by and between SANUWAVE, Inc. and Barry J. Jenkins. (Management compensation plan or arrangement) (Incorporate by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 10.9 Second Amendment to Management Stockholders Agreement, dated as of September 25, 2009, among SANUWAVE, Inc., Prides Capital Fund I, L.P. and certain shareholders of SANUWAVE, Inc. (Incorporate by reference to the Form 8-K filed with the SEC on September 30, 2009).
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
- 32.1 Section 1350 Certification of the Chief Executive Officer.
- 32.2 Section 1350 Certification of the Chief Financial Officer.

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**SIGNATURES**

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

Dated: November 16, 2009

**SANUWAVE HEALTH, INC.**

By: /s/ Christopher M. Cashman

**Christopher M. Cashman**

Chief Executive Officer and President

By: /s/ Barry J. Jenkins

**Barry J. Jenkins**

Chief Financial Officer

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