SANUWAVE Health, Inc. Form 10-Q November 19, 2018

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, 2018

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

For the transition period from _____ to

Commission File Number 000-52985

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

Nevada 20-1176000 (State or other jurisdiction of incorporation or organization) Identification No.)

3360 Martin Farm Road, Suite 100

Suwanee, GA 30024

(Address of principal executive offices) (Zip Code)

(770) 419-7525

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 9, 2018, there were issued and outstanding 155,533,303 shares of the registrant's common stock, \$0.001 par value.

SANUWAVE Health, Inc.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of SANUWAVE Health, Inc. and its subsidiaries ("SANUWAVE" or the "Company") contains forward-looking statements. All statements in this Quarterly Report on Form 10-Q, including those made by the management of the Company, other than statements of historical fact, are forward-looking statements. Examples of forward-looking statements include statements regarding the Company's future financial results, operating results, and projected costs; market acceptance of and demand for dermaPACE and our product candidates; management's plans and objectives for future operations; industry trends; regulatory actions that could adversely affect the price of or demand for our approved products; our intellectual property portfolio; our business, marketing and manufacturing capacity and strategy; estimates regarding our capital requirements, the anticipated timing of the need for additional funds, and our expectations regarding future capital-raising transactions, including potential tender offers for certain of our outstanding series of warrants; product liability claims; economic conditions that could adversely affect the level of demand for our products; timing of clinical studies and eventual FDA approval of our products; financial markets; and the competitive environment. 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," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" and "continue," the negative of these terms, or other compara terminology. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in the reports we file with the Securities and Exchange Commission (the "SEC"), specifically the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018 and in the Company's Quarterly Reports on Form 10-Q. Other risks and uncertainties are and will be disclosed in the Company's prior and future SEC filings. These and many other factors could affect the Company's future financial condition and operating results and could cause actual results to differ materially from expectations based on forward-looking statements made in this document or elsewhere by the Company or on its behalf. The Company undertakes no obligation to revise or update any forward-looking statements. The following information should be read in conjunction with the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018.

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.

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PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

SANUWAVE HEALTH, INC. AND SUBSIDIARIES. CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30,	December 31,
	2018	2017
ASSETS	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$72,311	\$730,184
Accounts receivable, net of allowance for doubtful accounts of \$42,950 in 2018 and \$92,797 in 2017 Inventory Prepaid expenses	152,706 240,973 168,480	152,520 231,532 90,288
TOTAL CURRENT ASSETS	634,470	1,204,524
PROPERTY AND EQUIPMENT, net	72,637	60,369
OTHER ASSETS	16,497 \$723,604	13,917
TOTAL ASSETS		\$1,278,810
LIABILITIES CURRENT LIABILITIES Accounts payable	\$1,560,965	\$1,496,523
Accrued expenses (Note 4)	746,083	673,600
Accrued employee compensation	364,503	1,680
Contract liabilities (Note 5)	353,115	-
Advances payable (Note 6) Line of credit, related parties (Note 7) Convertible promissory notes, net (Note 8) Short term notes payable (Note 10)	144,000 524,869 2,548,325 186,981	310,000 370,179 455,606

	0 0	,				
	Accrued interest, related parties (Note 11) Warrant liability (Note 13) Notes payable, related parties, net (Note 11)	1,005,144 1,396,199 5,335,243	685,907 1,943,883 5,222,259			
	TOTAL CURRENT LIABILITIES	14,165,427	11,159,637			
	NON-CURRENT LIABILITIES					
	Contract liabilities (Note 5)	25,959	-			
	TOTAL NON-CURRENT LIABILITIES	25,959	-			
	TOTAL LIABILITIES	14,191,386	11,159,637			
	COMMITMENTS AND CONTINGENCIES					
	STOCKHOLDERS' DEFICIT PREFERRED STOCK, par value \$0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-			
	PREFERRED STOCK, SERIES A CONVERTIBLE, par value	ue \$0.001,				
	6,175 designated; 6,175 shares issued and 0 shares outstanding					
	in 2018 and 2017	-	-			
	PREFERRED STOCK, SERIES B CONVERTIBLE, par value \$0.001,					
	293 designated; 293 shares issued and 0 shares outstanding in 2018 and 2017	-	-			
COMMON STOCK, par value \$0.001, 350,000,000 shares authorized;						
	155,107,127 and 139,300,122 issued and outstanding in 2018 and					
	2017, respectively (Note 12)	155,107	139,300			
	ADDITIONAL PAID-IN CAPITAL	100,979,533	94,995,040			
	ACCUMULATED DEFICIT	(114,541,440)	(104,971,384)			
	ACCUMULATED OTHER COMPREHENSIVE LOSS TOTAL STOCKHOLDERS' DEFICIT	(60,982) (13,467,782)	(43,783) (9,880,827)			
	TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$723,604	\$1,278,810			

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

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SANUWAVE HEALTH, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended	Three Months Ended	Nine Months Ended	Nine Months Ended
	September 30,	September 30,	September 30,	September 30,
	2018	2017	2018	2017
REVENUES				
Product	\$240,759	\$143,234	\$703,054	\$356,911
License fees	335,697	6,250	623,570	36,050
Other revenue	19,333	12,101	66,647	29,238
TOTAL REVENUES	595,789	161,585	1,393,271	422,199
COST OF REVENUES				
Product	151,624	56,415	413,447	105,027
Other	31,970	5,269	102,256	36,496
TOTAL COST OF REVENUES	183,594	61,684	515,703	141,523
GROSS MARGIN	412,195	99,901	877,568	280,676
OPERATING EXPENSES				
Research and development	661,736	266,837	1,379,517	965,084
General and administrative	2,415,106	475,377	5,391,511	1,875,891
Depreciation	5,709	5,465	16,733	17,543
	-	-	3,170	-

Loss on sale of property and equipment				
TOTAL OPERATING EXPENSES	3,082,551	747,679	6,790,931	2,858,518
OPERATING LOSS	(2,670,356)	(647,778)	(5,913,363)	(2,577,842)
OTHER INCOME (EXPENSE)				
Gain (loss) on warrant valuation adjustment	2,241,008	(41,681)	428,846	316,952
Interest expense	(395,604)	(160,978)	(4,070,326)	(496,997)
Loss on foreign currency exchange	(190)	(888)	(15,213)	(2,907)
TOTAL OTHER INCOME (EXPENSE), NET	1,845,214	(203,547)	(3,656,693)	(182,952)
NET LOSS	(825,142)	(851,325)	(9,570,056)	(2,760,794)