

**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, 2024

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.)

**11495 Valley View Road
Eden Prairie, MN**

(Address of principal executive offices)

55344

(Zip Code)

(952) 656-1029

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	N/A	N/A

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:

Large accelerated filer

Non-accelerated filer

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 6, 2024, there were issued and outstanding 8,534,151 shares of the registrant's common stock, \$0.001 par value per share.

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,” the “Company,” “we,” “us,” and “our”) 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: our results of operations, liquidity, and operations, restrictions and new regulations on our operations and processes, including the execution of clinical trials; the Company’s future financial results, operating results, and projected costs; market acceptance of and demand for UltraMIST and PACE®; success of future business development and acquisition activities; 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 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing agreements, or raising capital through the conversion of outstanding warrants or issuances of securities; product liability claims; economic conditions that could adversely affect the level of demand for or the cost of our products; timing of clinical studies and any eventual U.S. Food and Drug Administration (“FDA”) approval of new products and new uses of our current products; financial markets; the competitive environment; supplier and customer disputes; and our plans to remediate our material weaknesses in our disclosure controls and procedures and our internal control over financial reporting. These forward-looking statements are based on management’s estimates, projections, and assumptions as of the date hereof and include the assumptions that underlie such statements. Forward-looking statements may contain words such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” and “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 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, 2023, filed on March 21, 2024. Other risks and uncertainties are and will be disclosed in the Company’s subsequent SEC filings, including this Quarterly Report on Form 10-Q. 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, 2023, filed on March 21, 2024.

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

PART I -- FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share data)

	September 30, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalent	\$ 3,259	\$ 1,797
Accounts receivable, net of allowance of \$1,056 and \$1,237, as of September 30, 2024 and December 31, 2023, respectively	2,836	3,314
Inventory	3,431	2,951
Prepaid expenses and other current assets	378	1,722
Total Current Assets	9,904	9,784
Property, equipment and other, net	774	938
Intangible assets, net	3,906	4,434
Goodwill	7,260	7,260
Total Non-current Assets	11,940	12,632
Total Assets	\$ 21,844	\$ 22,416
LIABILITIES		
Current Liabilities:		
Senior secured debt, in default	\$ 24,426	\$ 18,278
Convertible promissory notes payable	4,817	5,404
Convertible promissory notes payable, related parties	2,838	1,705
Asset-backed secured promissory notes payable	-	3,117
Asset-backed secured promissory notes, related parties	-	1,458
Promissory note payable, related party	500	-
Accounts payable	4,137	5,705
Accrued expenses	5,241	5,999
Factoring liabilities	1,938	1,490
Warrant liability	35,509	14,447
Accrued interest	643	5,444
Accrued interest, related parties	952	669
Current portion of contract liabilities	137	92
Other	375	947
Total Current Liabilities	81,513	64,755
Non-current Liabilities		
Lease liabilities, less current portion	236	492
Contract liabilities, less current portion	358	347
Total Non-current Liabilities	594	839
Total Liabilities	\$ 82,107	\$ 65,594

Commitments and Contingencies (Note 14)

STOCKHOLDERS' DEFICIT

Preferred Stock, par value \$0.001, 5,000,000 shares authorized; 6,175 shares Series A, 293 shares Series B, 90 shares Series C and 8 shares Series D authorized; no shares issued and outstanding at September 30, 2024 and December 31, 2023	\$	-	\$	-
Common stock, par value \$0.001, 2,500,000,000 shares authorized; 3,150,062 and 3,041,492 issued and outstanding at September 30, 2024 and December 31, 2023, respectively *		3		3
Additional paid-in capital		178,397		176,979
Accumulated deficit		(238,673)		(220,049)
Accumulated other comprehensive income (loss)		10		(111)
Total Stockholders' Deficit		<u>(60,263)</u>		<u>(43,178)</u>
Total Liabilities and Stockholders' Deficit	\$	<u>21,844</u>	\$	<u>22,416</u>

* Reflects a one-for-three hundred seventy-five (1:375) reverse stock split of the outstanding shares of the Company's common stock effected on October 18, 2024

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

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

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ 9,360	\$ 4,953	\$ 22,308	\$ 13,404
Cost of Revenues	2,293	1,412	5,799	3,876
Gross Margin	7,067	3,541	16,509	9,528
Operating Expenses:				
General and administrative	2,545	2,681	8,059	6,678
Selling and marketing	2,202	1,039	4,468	3,430
Research and development	161	165	519	436
Depreciation and amortization	206	187	568	563
Total Operating Expenses	5,114	4,072	13,614	11,107
Operating Income (Loss)	1,953	(531)	2,895	(1,579)
Other Income (Expense):				
Interest expense	(3,315)	(2,907)	(9,948)	(10,125)
Interest expense, related party	(346)	(938)	(1,056)	(2,379)
Gain on extinguishment of debt	-	-	5,205	-
Change in fair value of derivative liabilities	(18,849)	(19,325)	(17,633)	(29,943)
Other expense	(106)	-	(893)	(16)
Other income	6	1	2,806	-
Total Other Expense	(22,610)	(23,169)	(21,519)	(42,463)
Net Loss	(20,657)	(23,700)	(18,624)	(44,042)
Other Comprehensive Loss				
Foreign currency translation adjustments	-	7	121	(6)
Total Comprehensive Loss	\$ (20,657)	\$ (23,693)	\$ (18,503)	\$ (44,048)
Net Loss per share:				
Basic and Diluted *	\$ (6.49)	\$ (9.95)	\$ (5.92)	\$ (24.15)
Weighted average shares outstanding:				
Basic and Diluted *	3,185	2,381	3,146	1,823

* Reflects a one-for-three hundred seventy-five (1:375) reverse stock split of the outstanding shares of the Company's common stock effected on October 18, 2024

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
 CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
 (UNAUDITED)
 (In thousands, except share data)

Three Months Ended September 30, 2024							
Common Stock							
	Number of Shares Issued and Outstanding	Par Value	Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total	
Balances as of June 30, 2024	3,150,062	\$ 3	\$ 178,397	\$ (218,016)	\$ 10	\$ (39,606)	
Net loss	-	-	-	(20,657)	-	(20,657)	
Balances as of September 30, 2024	<u>3,150,062</u>	<u>\$ 3</u>	<u>\$ 178,397</u>	<u>\$ (238,673)</u>	<u>\$ 10</u>	<u>\$ (60,263)</u>	

Three Months Ended September 30, 2023							
Common Stock							
	Number of Shares Issued and Outstanding	Par Value	Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total	
Balances as of June 30, 2023	1,497,700	\$ 2	\$ 153,824	\$ (214,584)	\$ (80)	\$ (60,838)	
Shares issued for settlement of debt	1,238,509	1	18,576	-	-	18,577	
Foreign currency translation adjustment	-	-	-	-	7	7	
Net loss	-	-	-	(23,700)	-	(23,700)	
Balances as of September 30, 2023	<u>2,736,209</u>	<u>\$ 3</u>	<u>\$ 172,400</u>	<u>\$ (238,284)</u>	<u>\$ (73)</u>	<u>\$ (65,954)</u>	

* Reflects a one-for-three hundred seventy-five (1:375) reverse stock split of the outstanding shares of the Company's common stock effected on October 18, 2024

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(UNAUDITED)
(In thousands, except share data)

Nine Months Ended September 30,

	Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balances as of December 31, 2023	3,041,492	\$ 3	\$ 176,979	\$ (220,049)	\$ (111)	\$ (43,178)
Shares issued for settlement of warrants	14,440	-	6	-	-	6
Shares issued for settlement of debt	94,130	-	1,412	-	-	1,412
Foreign currency translation adjustment	-	-	-	-	121	121
Net loss	-	-	-	(18,624)	-	(18,624)
Balances as of September 30, 2024	3,150,062	\$ 3	\$ 178,397	\$ (238,673)	\$ 10	\$ (60,263)

Nine Months Ended September 30, 2023

	Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balances as of December 31, 2022	1,463,300	\$ 1	\$ 153,298	\$ (194,242)	\$ (67)	\$ (41,010)
Shares issued for services	34,400	1	526	-	-	527
Shares issued for settlement of debt	1,238,509	1	18,576	-	-	18,577
Foreign currency translation adjustment	-	-	-	-	(6)	(6)
Net loss	-	-	-	(44,042)	-	(44,042)
Balances as of September 30, 2023	2,736,209	\$ 3	\$ 172,400	\$ (238,284)	\$ (73)	\$ (65,954)

* Reflects a one-for-three hundred seventy five (1:375) reverse stock split of the outstanding shares of the Company's common stock effected on October 18, 2024

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

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

	Nine Months Ended September 30,	
	2024	2023
Cash Flows - Operating Activities:		
Net Loss	\$ (18,624)	\$ (44,042)
Adjustments to reconcile net loss to net cash used by operating activities		
Depreciation and amortization	736	780
Bad debt expense	16	547
Shares issued for services	-	224
Gain on extinguishment of debt	(5,205)	-
Change in fair value of derivative liabilities	17,633	29,943
Amortization of debt issuance costs and original issue discount	4,792	5,656
Accrued interest	2,749	5,529
Changes in operating assets and liabilities		
Accounts receivable	66	253
Inventory	(480)	(844)
Prepaid expenses and other assets	225	(487)
Accounts payable	(1,013)	464
Accrued expenses	763	(1,326)
Contract liabilities	56	50
Net Cash Provided by (Used in) Operating Activities	<u>1,714</u>	<u>(3,253)</u>
Cash Flows - Investing Activities		
Proceeds from sale of property and equipment	-	13
Purchase of property and equipment	(254)	(169)
Net Cash Flows Used in Investing Activities	<u>(254)</u>	<u>(156)</u>
Cash Flows - Financing Activities		
Proceeds from convertible promissory notes	-	1,202
Payment of note payable	(2,175)	-
Proceeds from convertible notes payable	1,300	-
Proceeds from promissory note payable, related party	500	-
Proceeds from bridge notes advance	-	2,994
Proceeds (Payments) from factoring, net	449	(710)
Payments of principal on finance leases	(193)	(130)
Net Cash Flow (Used in) Provided by Financing Activities	<u>(119)</u>	<u>3,356</u>
Effect of Exchange Rates on Cash	<u>121</u>	<u>(5)</u>
Net Change in Cash During Period	1,462	(58)
Cash at Beginning of Period	1,797	1,153
Cash at End of Period	<u>\$ 3,259</u>	<u>\$ 1,095</u>
Supplemental Information:		
Cash paid for interest	<u>\$ 3,189</u>	<u>\$ 984</u>

Non-cash Investing and Financing Activities:		
Shares issued for settlement of debt	1,412	-
Write off deferred merger costs	1,226	-
Warrants issued in conjunction with convertible promissory notes	3,633	570
Conversion of convertible notes payable to common stock	-	18,577
Capitalize default interest into senior secured debt	3,850	-
Conversion of asset-based secured promissory notes to convertible promissory notes	4,584	-
Embedded conversion feature on convertible promissory notes payable	-	(520)
Common shares issued for advisory shares	-	302

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2024

1. Nature of the Business and Basis of Presentation

SANUWAVE Health, Inc. and subsidiaries (“SANUWAVE” or the “Company”) is focused on the commercialization of its patented noninvasive and biological response activating medical systems for the repair and regeneration of skin, musculoskeletal tissue, and vascular structures.

Basis of Presentation - The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all the information and disclosures required by U.S. GAAP for comprehensive financial statements.

The financial information as of September 30, 2024, and for the three and nine months ended September 30, 2024, and 2023 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair statement have been included. Operating results for the three and nine months ended September 30, 2024, are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2024.

The condensed consolidated balance sheet on December 31, 2023, has been derived from the audited consolidated financial statements at that date but does not include all the information and disclosures required by U.S. GAAP for comprehensive financial statements. These financial statements should be read in conjunction with the Company’s December 31, 2023, Annual Report on Form 10-K filed with the SEC on March 21, 2024 (the “2023 Annual Report”).

Reverse Stock Split - All share numbers, including the number of shares underlying warrants, options and convertible debt, and per share amounts presented in these financial statements, including these footnotes reflect a one-for-three hundred seventy five (1:375) reverse stock split of the outstanding shares of the Company's common stock effected on October 18, 2024 (the "Reverse Stock Split"). The Company's authorized shares of common and preferred stock along with the par value did not change. No fractional shares will be issued as a result of the reverse stock split. Any fractional shares that would have resulted from the reverse stock split will be settled in cash. The reverse stock split will affect all common stockholders uniformly and will not alter any stockholder's percentage interest in the Company's common stock, except to the extent that the reverse stock split results in some stockholders experiencing an adjustment of a fractional share as described above.

2. Going Concern

The events of default on the Company’s senior secured debt as of September 30, 2024 and the working capital deficit have raised substantial doubt as to our ability to continue as a going concern for a period of at least twelve months from the filing of this Form 10-Q. We may be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so, and/or the terms of any financing may not be advantageous to us.

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources for the commercialization of UltraMIST and PACE systems which will require additional capital resources to remain a going concern.

Management’s plans may include obtaining additional capital in 2024. The Company could obtain additional capital through the conversion of outstanding warrants, issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company’s existing stockholders. In addition, there can be no assurances that any plans to obtain additional capital will be successful on the terms or timeline the Company expects, or at all. If these efforts are unsuccessful, the Company may be required to significantly curtail or discontinue operations or, if available, obtain funds through financing transactions with unfavorable terms.

The accompanying condensed consolidated financial statements have been prepared in conformity with U.S. GAAP, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in

the normal course of business. The carrying amounts of assets and liabilities presented in the condensed consolidated financial statements do not necessarily purport to represent realizable or settlement values. The condensed consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. The Company's condensed consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

3. Summary of Significant Accounting Policies

Significant accounting policies followed by the Company are summarized below and should be read in conjunction with those described in Note 3 of the consolidated financial statements in our 2023 Annual Report.

Estimates - These condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. Because a precise determination of assets and liabilities, and correspondingly revenues and expenses, depend on future events, the preparation of condensed consolidated financial statements for any period necessarily involves the use of estimates and assumptions. Actual amounts may differ from these estimates. These condensed consolidated financial statements have, in management's opinion, been properly prepared within reasonable limits of materiality and within the framework of the accounting policies summarized herein.

Significant estimates include the recording of allowances for credit losses, the net realizable value of inventory, fair value of goodwill and other intangible assets, the determination of the valuation allowances for deferred taxes, litigation contingencies, and the estimated fair value of financial instruments, including warrants and embedded conversion options.

Revenue Recognition - The core principle of Accounting Standards Codification ("ASC") Topic 606 "Revenue from Contracts with Customers" ("ASC 606") requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company allocates the transaction price to all contractual performance obligations included in the contract. If a contract has more than one performance obligation, we allocate the transaction price to each performance obligation based on stand-alone selling price, which depicts the amount of consideration we expect to be entitled in exchange for satisfying each performance obligation. The Company recognizes revenue primarily from the following types of contracts:

System Sales, Consumables and Part Sales - System sales, consumables and part sales include devices and applicators (new and refurbished). Performance obligations are satisfied at the point in time when the customer obtains control of the goods, which is generally at the point in time that the product is shipped.

Other Revenue - Other revenue primarily includes warranties, repairs, and billed freight. The Company allocates the device sales price to the product and the embedded warranty by reference to the stand-alone extended warranty price. Warranty revenue is recognized over the time that the Company satisfies its performance obligations, which is generally the warranty term. Repairs (parts and labor) and billed freight revenue are recognized at the point in time that the service is performed, or the product is shipped, respectively.

Deferred Offering Costs - Deferred stock offering costs represent amounts paid for legal, consulting, and other offering expenses directly attributable to the offering of securities in conjunction with the recapitalization under the Merger Agreement (as defined in Note 4), as defined and further described in Note 4, and are deferred and charged against the gross proceeds of the offering. In the event of a significant delay or cancellation of a planned offering of securities, all the costs would be expensed. In June 2024, the Company terminated the Merger Agreement and the deferred offering costs of \$0.5 million were expensed.

Recent Accounting Pronouncements - In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU) No. 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures which will require companies to disclose significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"). The pronouncement is effective for annual filings for the year ended December 31, 2024. The Company is still assessing the impact of the adoption of this standard but does not expect it to have a material impact on its results of operations, financial position or cash flows.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. Update No. 2023-09 aims to enhance the transparency and decision usefulness of income tax disclosures. Update No.

2023-09 modifies the rules on income tax disclosures to require entities to disclose (1) specific categories in the rate reconciliation, (2) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (3) income tax expense or benefit from continuing operations (separated by federal, state, and foreign). Update 2023-09 also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. Update No. 2023-09 is effective for fiscal years beginning after December 15, 2024. We expect to adopt Update No. 2023-09 prospectively. We are currently evaluating the potential impact of adopting this new guidance on our condensed consolidated financial statements and related disclosures.

4. Merger Agreement

On August 23, 2023, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with SEP Acquisition Corp., a Delaware corporation (“SEPA”), and SEP Acquisition Holdings Inc., a Nevada corporation and a wholly owned subsidiary of SEPA. Pursuant to the terms of the Merger Agreement, a business combination between the Company and SEPA was to be effected.

On June 25, 2024, the Company delivered a notice to SEPA terminating the Merger Agreement.

5. Net Loss per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares outstanding for the three and nine months ended September 30, 2024 and 2023. The weighted average number of shares outstanding includes outstanding common stock and shares issuable for nominal consideration. Accordingly, warrants issued with a \$0.01 per share exercise price, are included in weighted average shares outstanding as follows:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Weighted average shares outstanding				
Common shares	3,150	2,323	3,103	1,765
Common shares issuable assuming exercise of nominally priced warrants	35	58	43	58
Weighted average shares outstanding	<u>3,185</u>	<u>2,381</u>	<u>3,146</u>	<u>1,823</u>

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding. To the extent that securities are “anti-dilutive,” they are excluded from the calculation of diluted net loss per share. As a result of the net loss for each the three and nine months ended September 30, 2024 and 2023, all potentially dilutive shares in such periods were anti-dilutive and therefore excluded from the computation of diluted net loss per share.

(in thousands)	Nine Months Ended	
	September 30, 2024	September 30, 2023
Common stock options	42	51
Common stock purchase warrants	3,963	2,951
Convertible notes payable, including interest	621	599
	<u>4,626</u>	<u>3,601</u>

6. Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	September 30, 2024	December 31, 2023
Registration penalties	\$ 1,583	\$ 1,583
License fees	-	892
Board of directors fees	1,192	942
Employee compensation	2,098	2,298
Other	368	284
	<u>\$ 5,241</u>	<u>\$ 5,999</u>

7. Senior Secured Debt, In Default

The following table summarizes outstanding senior secured debt, in default:

(in thousands)	September 30, 2024				December 31, 2023			
	Principal	Debt Discount	Carrying Value	Accrued Interest	Principal	Debt Discount	Carrying Value	Accrued Interest
Senior secured debt	\$ 26,613	\$ (2,187)	\$ 24,426	-	\$ 21,562	\$ (3,284)	\$ 18,278	\$ 3,206

Senior secured promissory note payable, in default (“Senior Secured Note”) –In August 2020, the Company entered into a Note and Warrant Purchase and Security Agreement (the “NWPSA”). In accordance with the NWPSA, the Company issued a \$15 million Senior Secured Promissory Note Payable (the “Senior Secured Note”) and a warrant exercisable for shares of the Company’s common stock in exchange for cash to support operations, repay outstanding debt and close on the acquisition of the UltraMIST assets from Celularity Inc. (Celularity) among other transactions.

In February 2022, the Company entered into a Second Amendment to Note and Warrant Purchase and Security Agreement (the “Second NWPSA”) for \$3.0 million, for a total of \$18.0 million outstanding. Along with the issuance of the note, the Company also issued warrants to purchase 43,200 shares of common stock with an exercise price of \$67.50 and 54,933 shares of common stock.

Interest is charged at the greater of the prime rate or 3% plus 9%. The principal increases at a rate of 3% of the outstanding principal balance (PIK interest) on each quarterly interest payment date. The original maturity date of the Senior Secured Note is September 20, 2025, and it can be prepaid.

In March 2024, the Company entered into a Consent, Limited Waiver and Fifth Amendment to Note and Warrant Purchase and Security Agreement (the “Fifth Amendment”). The Fifth Amendment provides (i) consent to enter into a License and Option Agreement and consummation of a License and Option Transaction a waiver of any event of default that may occur under the NWPSA, because of the License and Option Agreement or License and Option Transaction and (iii) amended the NWPSA to release certain patents from the collateral. The Fifth Amendment also provides for a forbearance of exercising remedies in connection with certain existing events of default under the NWPSA until the earlier of (x) the occurrence of another event of default under the NWPSA or (y) April 30, 2024. During the forbearance period, the outstanding obligations under the NWPSA continue to accrue interest at the default rate.

As of September 30, 2024, the Company is in default on the minimum liquidity provisions in the Senior Secured Note and, as a result, it is classified in current liabilities in the accompanying condensed consolidated balance sheets. As of September 30, 2024, the Company was accruing interest at the default interest rate of an incremental 5%.

The debt issuance costs, and debt discount related to the Senior Secured Note were capitalized as a reduction in the principal amount and are being amortized to interest expense over the life of the Senior Secured Note.

The following table summarizes the amortization and interest expense related to the Senior Secured Note:

(In millions)	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Amortization of debt issuance costs and debt discount, included in interest expense	\$ 0.5	\$ 0.5	\$ 1.4	\$ 1.4
Interest expense	\$ 2.1	\$ 1.8	\$ 6.1	\$ 5.1

On July 15, 2024, the Company entered into the Sixth Amendment to Note and Warrant Purchase and Security Agreement (the “Sixth Amendment”), which was a modification of debt. The Sixth Amendment added, as of June 30, 2024, a consent fee of \$0.7 million to the principal amount of the Senior Secured Note issued pursuant to the NWPSA. On and after April 1, 2024, for each fiscal quarter during which any interest is payable in cash, deferred interest and default interest shall be calculated based on the principal amount of the Senior Secured Note as of the beginning of the quarter and shall include any default interest accrued to date. The Sixth Amendment also provides for a forbearance of exercising remedies in connection with certain existing events of default under the NWPSA until the earlier of (x) the occurrence of another event of default under the NWPSA or (y) December 31, 2024. During the forbearance period, the outstanding obligations under the NWPSA continue to accrue interest at the default rate.

8. Promissory Notes Payable

The following two tables summarize outstanding notes payable as of September 30, 2024, and December 31, 2023:

(In thousands, except conversion price)	As of September 30, 2024				
	Conversion Price	Principal	Remaining Debt Discount	Remaining Embedded Conversion Option	Carrying Value
Historical convertible promissory notes payable, related parties, in default	\$ 37.50	1,373	-	-	1,373
Convertible notes payable	\$ 15.00	6,056	(1,401)	162	4,817
Convertible notes payable, related parties	\$ 15.00	1,662	(240)	43	1,465
Total Convertible Promissory Notes Payable		<u>\$ 9,091</u>	<u>\$ (1,641)</u>	<u>\$ 205</u>	<u>\$ 7,655</u>

(In thousands, except conversion price)	As of December 31, 2023			
	Conversion Price	Principal	Remaining Debt Discount	Carrying Value
Acquisition convertible promissory note, in default	\$ 37.50	4,000	-	4,000
Historical convertible promissory note, related party, in default	\$ 37.50	1,373	-	1,373
Convertible notes payable	\$ 15.00	2,639	(1,235)	1,404
Convertible notes payable, related parties	\$ 15.00	450	(118)	332
Total Convertible Promissory Notes Payable		<u>\$ 8,462</u>	<u>\$ (1,353)</u>	<u>\$ 7,109</u>

Convertible Notes Payable and Convertible Notes Payable, Related Parties –In August 2022, November 2022, May 2023, December 2023, January 2024, and June 2024, the Company entered into Securities Purchase Agreements (the “Purchase Agreements”), for the sale in a private placement of (i) Future Advance Convertible Promissory Notes (the “Notes”) in an

aggregate principal amount of approximately \$16.2 million in August 2022, approximately \$4.0 million in November 2022, \$1.2 million in May 2023, \$1.9 million in December 2023, \$4.6 million in January 2024 related to the conversion of the Asset-Backed Secured Promissory Notes (described in Note 9) and \$1.3 million in June 2024 (ii) Common Stock Purchase Warrants to purchase an additional 1.9 million shares of common stock with an exercise price of \$25.13 per share and (iii) Common Stock Purchase Warrants to purchase an additional 1.9 million shares of common stock with an exercise price of \$15.00 per share. Interest expense for the three and nine months ended September 30, 2024, totaled \$1.5 million and \$4.3 million, respectively. Interest expense for the three and nine months ended September 30, 2023, totaled \$1.3 million and \$6.0 million, respectively.

The Notes have a term of 12 months from the date of issue. Pursuant to the Notes, the Company promised to pay in cash and/or in shares of common stock, at a conversion price of \$15.00 (the “Conversion Price”), the principal amount and interest at a rate of 15% per annum on any outstanding principal. The Conversion Price of the Notes is subject to adjustment, including if the Company issues or sells shares of common stock for a price per share less than the Conversion Price of the Notes or if the Company lists its shares of common stock on The Nasdaq Capital Market and the average volume weighted average price of such common stock for the five trading days preceding such listing is less than \$15.00 per share; provided, however, that the Conversion Price shall never be less than \$3.75. The Notes contain customary events of default and covenants, including limitations on incurrence of indebtedness and liens.

In May 2024 the Company utilized its election to convert the May issued Notes into shares of common stock upon the Notes' maturity. The May notes totaling \$1.2 million in principal and \$0.2 million interest were converted to 0.1 million shares of common stock.

Promissory Note Payable, Related Parties - In June 2024 the Company entered into a \$0.5 million promissory note with a related party. Interest is being accrued at 12% and the note matures on December 3, 2024.

9. Asset-Backed Secured Promissory Notes

In July 2023, the Company issued Asset-Backed Secured Promissory Notes (the “ABS Promissory Notes”) in an aggregate principal amount of \$4.6 million to certain accredited investors (the “Purchasers”) at an original issue discount of 33.33%. The ABS Promissory Notes bear an interest rate of 0% per annum and mature on January 21, 2024 (the “Maturity Date”). The Company received total proceeds of approximately \$3.0 million. The Company entered into a Security Agreement providing for a continuing and unconditional security interest in any and all property of the Company. This security interest is subordinate to the Senior Secured Debt described in Note 7. Interest expense for the nine months ended September 30, 2024, totaled \$0.1 million prior to conversion at the Maturity Date.

On January 21, 2024, pursuant to the side letter, the Company issued each Purchaser a Convertible Note Payable with the same principal amount as the principal amount of such Purchasers' ABS Promissory Notes. Pursuance to this side letter the ABS Promissory Notes converted to convertible promissory notes, as described in Note 8. The Company recorded a net loss on extinguishment of debt totaling \$0.1 million for the nine months ended September 30, 2024.

10. Fair Value Measurements

The Company uses various inputs to measure the outstanding warrants and certain embedded conversion features associated with a convertible debt on a recurring basis to determine the fair value of the liabilities.

The following tables classify the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy:

Fair value measured at September 30, 2024				
(in thousands)	Fair value at September 30, 2024	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 35,509	\$ -	\$ -	\$ 35,509
Embedded conversion option	205	-	-	205
Total fair value	\$ 35,714	\$ -	\$ -	\$ 35,714

Fair value measured at December 31, 2023				
(in thousands)	Fair value at December 31, 2023	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 14,447	\$ -	\$ -	\$ 14,447
Embedded conversion option	93	-	-	93
Total fair value	\$ 14,540	\$ -	\$ -	\$ 14,540

There were no transfers among Levels 1, 2 or 3 during the three and nine months ended September 30, 2024, and 2023. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

Warrant Liability

The Company's liability classified warrants as of September 30, 2024, and the value of the initial warrant liability from the June financing, were valued using a probability weighted expected value considering the proposed reverse stock split of the Company's common stock (the "Reverse Stock Split") that will effectuate the exchange of Notes and Common Stock Purchase Warrants for shares of the Company's common stock (the "Note and Warrant Exchange"), and the previous Black Scholes valuation model, with significant value stemming from the Note and Warrant Exchange. Significant inputs under the Note and Warrant Exchange included the expected exchange ratio of 0.90 for \$15.00 warrants and 0.85 for \$25.13 warrants, the value of the Company's common stock, the expected timing of the Reverse Stock Split effectuating, and the probability of the Note and Warrant Exchange occurring (90% probability).

The Company's liability classified warrants as of December 31, 2023 and the value of initial warrant liability from the conversion of the ABS Promissory Notes, were valued using a probability weighted expected value considering the Merger Agreement and the previous Black Scholes valuation model, with significant value stemming from the Merger Agreement. Significant inputs under the Merger Agreement valuation included the expected exchange ratio 0.003, the value of SEPA's Class A Common Stock, the expected timing of the closing of the Merger, and the probability of the Merger closing.

A summary of the warrant liability activity for the nine months ended September 30, 2024, is as follows:

(in thousands, except per share data)	Warrants Outstanding	Fair Value per Share	Fair Value (in thousands)
Balance at December 31, 2023	3,257	\$ 4.44	\$ 14,447
Issuance	781	4.65	3,633
Exercised warrants	(23)	3.75	-
Loss on remeasurement of warrant liability	-		17,429
Balance at September 30, 2024	<u>4,015</u>	<u>\$ 8.84</u>	<u>\$ 35,509</u>

Embedded Conversion Option Liability

Certain convertible notes include a conversion option that meets the definition of a derivative liability and, accordingly, is required to be bifurcated. The fair value for the conversion option liability was valued using a probability weighted expected value considering the proposed Reverse Stock Split of the Company's common stock that will effectuate the Note and Warrant Exchange, and the previous Black Scholes valuation model, with significant value stemming from the Note and Warrant Exchange. Significant inputs under the Note and Warrant Exchange included the expected exchange ratio of 0.90 for \$15.00 warrants and 0.85 for \$25.13 warrants, the value of the Company's common stock, the expected timing of the Reverse Stock Split effectuating, and the probability of the Note and Warrant Exchange occurring (90% probability).

A summary of the conversion option liability activity for the nine months ended September 30, 2024, is as follows:

(in thousands, except per share data)	Conversion Options Outstanding
Balance at December 31, 2023	\$ 93
Loss on remeasurement of conversion liability	112
Balance at September 30, 2024	<u>\$ 205</u>

11. Revenue

The disaggregation of revenue is based on type and geographical region. The following table presents revenue from contracts with customers:

	Three Months Ended September 30, 2024			Three Months Ended September 30, 2023		
	United States	International	Total	United States	International	Total
Consumables and parts revenue	\$ 5,611	\$ 9	\$ 5,620	\$ 3,133	\$ 25	\$ 3,158
System revenue	3,649	12	3,661	1,607	18	1,625
License fees and other	-	10	10	38	-	38
Product Revenue	\$ 9,260	\$ 31	\$ 9,291	\$ 4,778	\$ 43	\$ 4,821
Rental Income	69	-	69	132	-	132
Total Revenue	<u>\$ 9,329</u>	<u>\$ 31</u>	<u>\$ 9,360</u>	<u>\$ 4,910</u>	<u>\$ 43</u>	<u>\$ 4,953</u>

	Nine Months Ended September 30,			Nine Months Ended September 30, 2023		
	United States	International	Total	United States	International	Total
Consumables and parts	\$ 14,773	\$ 106	\$ 14,879	\$ 8,620	\$ 76	\$ 8,696
System revenue	7,061	83	7,144	3,763	132	3,895
License fees and other	-	30	30	121	15	136
Product Revenue	\$ 21,834	\$ 219	\$ 22,053	\$ 12,504	\$ 223	\$ 12,727
Rental Income	255	-	255	677	-	677
Total Revenue	\$ 22,089	\$ 219	\$ 22,308	\$ 13,181	\$ 223	\$ 13,404

12. Concentration of Credit Risks and Limited Suppliers

Major customers are defined as customers whose accounts receivable or sales individually consist of more than 10% of trade receivables or total sales, respectively. The percentage of accounts receivable from major customers of the Company for the periods indicated were as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Revenue:				
Customer A	15%	n/a	n/a	n/a

The Company currently purchases most of its product component materials from single suppliers and the loss of any of these suppliers could result in a disruption in the Company's production. The percentage of purchases from major vendors of the Company that exceeded ten percent of total purchases for the three and nine months ended September 30, 2024, and 2023 were as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Purchases:				
Vendor A	33%	22%	25%	19%
Vendor B	n/a	23%	n/a	16%
Vendor C	n/a	20%	n/a	10%

13. License and Option Agreement

In March 2024, the Company entered into an exclusive license and option agreement (the "Patent License") with a third-party licensee in connection with a portfolio of patents related to the field of intravascular shockwave applications. The Company received a one-time payment of \$2.5 million related to this Patent License, which was recorded in other income during the nine months ended September 30, 2024. The Company granted the Licensee an exclusive license to the patents and an option to acquire the patents for an additional one-time payment in the mid single-digit millions of dollars for a period of 3 years following the effective date of the Agreement. Upon acquisition of the patents, the Licensee will distribute any resulting proceeds to the Company, including but not limited to any royalties, license fees, settlement payments, or other proceeds generated from the licensing or assertion of the patents, in accordance with a revenue sharing agreement. If the Licensee does not exercise its option to acquire the Patents during a specified option period of 3 years from the effective date of the Agreement, the license terminates, a supplement license fee is owed, and all rights revert back to the Company.

Contingent Consideration - The Company considers such royalties, license fees, settlement payments, or other proceeds as variable or contingent consideration. The Company determined that the amount of variable consideration would be constrained until the period the uncertainty related to the consideration is relieved.

14. Commitments and Contingencies

In the ordinary course of business, the Company from time to time becomes involved in various legal proceedings involving a variety of matters. The Company does not believe there are any pending legal proceedings that will have a material adverse effect on the Company's business, consolidated financial position, results of operations, or cash flows. However, the outcome of such legal matters is inherently unpredictable and subject to significant uncertainties. The Company expenses legal fees in the period in which they are incurred.

Termination Agreement – In February 2024, the Company entered into a termination agreement with an advisor to agree on termination fees owed with respect to a previous engagement agreement. The Company agreed to a contingent payment of \$0.7 million upon the closing of the Merger disclosed in Note 4. Upon the Company's termination of the Merger Agreement in June 2024, the related contingent consideration liability was derecognized.

Acquisition dispute – In May 2021, the Company received notification alleging that it is not in compliance with the license agreement with Celularity entered into in connection with the acquisition of the UltraMIST assets. The Company has settled this dispute in June 2024 for a settlement amount of \$2.2 million, which resulted in the removal of \$4.0 million in convertible promissory note payable, \$2.4 million in accrued interest, \$0.9 million of accrued expenses, \$0.5 million of other liabilities, and \$0.4 million in accounts receivable, which resulted in the recognition of a gain on extinguishment of debt of \$5.3 million.

15. Subsequent Events

Consent and Limited Waiver

On October 17, 2024, the Company entered into a Consent and Limited Waiver to Note and Warrant Purchase and Security Agreement (the "Consent and Limited Waiver") with respect to that certain NWPSA, with the noteholders party thereto (the "Holders") and NH Expansion Credit Fund Holdings LP, as agent (the "Agent"). The Agent and the Holders agreed to continue to forbear upon exercising remedies in connection with certain existing events of default under the NWPSA until the earlier of (x) the occurrence of an event of default and (y) December 31, 2024. The Consent and Limited Waiver also consents to the repayment in full of amounts owed to HealthTronics, Inc. ("HealthTronics") pursuant to the Convertible Promissory Note, dated as of August 6, 2020, by and between the Company and HealthTronics, in the original principal amount of approximately \$1.4 million (the "HealthTronics Note"); the Private Placement (as defined below) and the Reverse Stock Split if the Company has at least \$5.0 million of liquidity following such transactions, which is required pursuant to the minimum liquidity covenant in the NWPSA. The Agent and the Holders have also agreed that any existing event of default that exists due to the Company's failure to meet the minimum liquidity covenant will be waived if the conditions set forth in the Consent and Limited Waiver, including at least \$5.0 million of liquidity following such transactions, are met. As a condition to the effectiveness of the Consent and Limited Waiver, the Agent exercised, on a cashless basis, all warrants issued by the Company to the Agent in exchange for the issuance of 146,302 shares (the "NWPSA Shares") of the Company's common stock following the Reverse Stock Split.

Private Placement of Common Stock

On October 16, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with the purchasers (the "Purchasers"), for the private placement (the "Private Placement") of approximately 1.3 million shares (the "Shares") of common stock at a purchase price of \$8.25 per share, in each case, after adjustment to reflect the Reverse Stock Split. The Private Placement closed on October 18, 2024, and aggregate gross proceeds were approximately \$10.3 million, before deducting offering expenses.

The Company used the net proceeds from the Private Placement to pay all amounts owed pursuant to the Consent and Limited Waiver and that certain letter agreement, dated as of August 8, 2024, between the Company and HealthTronics with respect to the HealthTronics Note, and intends to use the remaining net proceeds for working capital and general corporate purposes, which may include the repayment of other indebtedness.

In addition, on October 16, 2024, the Company and the Purchasers entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which the Company agreed to file the registration statement with the SEC on or before December 17, 2024 (subject to certain exceptions) for purposes of registering the resale of the Placement Shares, to use its commercially reasonable efforts to have such registration statement declared effective within the time period set forth in the Registration Rights Agreement, and to keep the registration statement effective until the date that all Placement Shares have been sold, thereunder or pursuant to Rule 144.

The HealthTronics Note was paid in full on October 22, 2024 and all related defaults were thus cured.

Note and Warrant Exchange

On October 18, 2024, effective upon the implementation of the Reverse Stock Split, the Company issued an aggregate of 3,989,456 shares of common stock in exchange for all outstanding Notes and Common Stock Purchase Warrants (“Warrants”) issued by the Company in private placements in August 2022, November 2022, May 2023, December 2023, January 2024 and June 2024. Pursuant to the Note and Warrant Exchange, (i) each outstanding Note was fully accelerated to maturity (with 15% interest paid on the outstanding principal) and then converted (per the terms of the Note) into shares of common stock at \$15.00 per share, (ii) each Warrant with an exercise price of \$15.00 per share was exchanged for 0.0024 shares of Common Stock per share subject to such Warrant, and (iii) each Warrant with an exercise price of \$25.13 per share was exchanged for approximately 0.0023 shares of Common Stock per share subject to such Warrant.

2024 Equity Incentive Plan

On October 18, 2024, the Company registered approximately 1.4 million shares of common stock available for issuance under the 2024 Equity Incentive Plan.

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, 2023 included in our Annual Report on Form 10-K, filed with the SEC on March 21, 2024 (the "2023 Annual Report").

Executive Summary

We continued to realize significant revenue growth during the three months ended September 30, 2024, as compared to the same period in 2023. Revenue for the three months ended September 30, 2024, totaled \$9.4 million, an increase of 89%, as compared to \$5.0 million for the same period of 2023. Revenue for the nine months ended September 30, 2024, totaled \$22.3 million, an increase of 66%, as compared to \$13.4 million for the same period of 2023.

Net loss for the three months ended September 30, 2024, was \$20.7 million compared to a net loss of \$23.7 million for the same period in 2023. The decrease in our net loss for the three months ended September 30, 2024, was primarily related to an increase in operating income and a decrease in change of fair value of derivative liabilities. For the three months ended September 30, 2024, our operating income totaled \$2.0 million, which is an improvement of \$2.5 million compared to the same period of 2023.

Net loss for the nine months ended September 30, 2024, was \$18.6 million, compared to a net loss of \$44.0 million for the same period in 2023. The decrease in our net loss for the nine months ended September 30, 2024, was primarily related to an increase in operating income, a decrease in change of fair value of derivative liabilities, a gain on the extinguishment of debt, and a one-time receipt related a third-party license and option agreement. For the nine months ended September 30, 2024, our operating income totaled \$2.9 million, which is an improvement of \$4.5 million compared to the same period of 2023.

All share numbers, including the number of shares underlying warrants, options and convertible debt, and per share amounts presented in these financial statements, including these footnotes reflect a one-for-three hundred seventy five (1:375) reverse stock split of the Company's common stock effected on October 18, 2024 (the "Reverse Stock Split"). The Company's authorized shares of common and preferred stock along with the par value did not change. No fractional shares will be issued as a result of the reverse stock split. Any fractional shares that would have resulted from the reverse stock split will be settled in cash. The reverse stock split will affect all common stockholders uniformly and will not alter any stockholder's percentage interest in the Company's common stock, except to the extent that the reverse stock split results in some stockholders experiencing an adjustment of a fractional share as described above.

Non-GAAP Financial Measures

Throughout this Management's Discussion and Analysis of Financial Condition and Results of Operations, we present certain financial measures that facilitate management's review of the operational performance of the Company and as a basis for strategic planning; however, such financial measures are not presented in our financial statements prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). These financial measures are considered "non-GAAP financial measures" and are intended to supplement, and should not be considered as superior to, or a replacement for, financial measures presented in accordance with U.S. GAAP.

The Company uses Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") and Adjusted EBITDA to assess its operating performance. Adjusted EBITDA is Earnings before Interest, Taxes, Depreciation and Amortization adjusted for the change in fair value of derivatives and any significant non-cash or non-recurring one-time charges. EBITDA and Adjusted EBITDA should not be considered as alternatives to net income as a measure of financial performance or any other performance measure derived in accordance with U.S. GAAP, and they should not be construed as an inference that our future results will be unaffected by unusual or non-recurring items. These non-GAAP financial measures are presented in a consistent manner for each period, unless otherwise disclosed. The Company uses these measures for the purpose of evaluating its historical and prospective financial performance, as well as its performance relative to competitors. These measures also help the Company to make operational and strategic decisions. The Company believes that providing this information to investors, in addition to GAAP measures, allows them to see the Company's results through the eyes of management, and to better understand its historical and future financial performance. These

non-GAAP financial measures are also frequently used by analysts, investors, and other interested parties to evaluate companies in our industry, when considered alongside other U.S. GAAP measures.

EBITDA and Adjusted EBITDA have their limitations as analytical tools, and you should not consider them in isolation or as a substitute for analysis of our results as reported under U.S. GAAP. Some of these limitations are that EBITDA and Adjusted EBITDA:

- Do not reflect every expenditure, future requirements for capital expenditures or contractual commitments.
- Do not reflect all changes in our working capital needs.
- Do not reflect interest expense, or the amount necessary to service our outstanding debt.

As presented in the U.S. GAAP to Non-GAAP Reconciliations section below, our non-GAAP financial measure excludes the impact of certain charges that contribute to our net loss.

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net Income/(Loss)	\$ (20,657)	\$ (23,700)	\$ (18,624)	\$ (44,042)
Non-GAAP Adjustments:				
Interest expense	3,661	3,845	11,004	12,504
Depreciation and amortization	256	266	736	780
EBITDA	(16,740)	(19,589)	(6,884)	(30,758)
Non-GAAP Adjustments for Adjusted EBITDA:				
Change in fair value of derivative liabilities	18,849	19,325	17,633	29,943
Other non-cash or non-recurring charges:				
Gain on extinguishment of debt	-	-	(5,205)	-
Severance agreement and legal settlement	-	-	585	-
Release of historical accrued expenses	-	-	(579)	(1,250)
Shares for services	-	-	-	224
License and option agreement	-	-	(2,500)	-
Prepaid legal fees expensed from termination of Merger Agreement	-	-	457	-
Adjusted EBITDA	\$ 2,109	\$ (264)	\$ 3,507	\$ (1,841)

Results of Operations

(in thousands)	For the Three Months Ended				For the Nine Months Ended			
	September 30,		Change		September 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Revenues:								
Total Revenue	\$ 9,360	\$ 4,953	\$4,407	89%	\$ 22,308	\$ 13,404	\$8,904	66%
Cost of Revenues	2,293	1,412	881	62%	5,799	3,876	1,923	50%
Gross Margin	7,067	3,541	3,526	100%	16,509	9,528	6,981	73%
Gross Margin %	76%	71%	401 bps		74%	71%	292 bps	
Operating Expenses:								
General and administrative	2,545	2,681	(136)	(5%)	8,059	6,678	1,381	21%
Selling and marketing	2,202	1,039	1,163	112%	4,468	3,430	1,038	30%
Research and Development	161	165	(4)	-2%	519	436	83	19%
Depreciation and amortization	206	187	19	10%	568	563	5	1%
Operating Income (Loss)	1,953	(531)	2,484	-468%	2,895	(1,579)	4,474	283%
Other Income (Expense)	(22,610)	(23,169)	559	2%	(21,519)	(42,463)	20,944	49%
Net Income (Loss)	<u><u>\$(20,657)</u></u>	<u><u>\$(23,700)</u></u>	<u><u>\$3,043</u></u>	13%	<u><u>\$(18,624)</u></u>	<u><u>\$(44,042)</u></u>	<u><u>\$25,418</u></u>	58%

Revenues and Gross Margin

Revenues for the three month-period ended September 30, 2024, were \$9.4 million compared to \$5.0 million for the same period of 2023, an increase of \$4.4 million, or 89%. The increase was primarily driven by the continued increased sales of our UltraMIST® system. The increase in revenues was partially due to an increase in the average selling price of our consumables and parts revenue of 26% year over year, and the remainder of the growth was related to an increase in the number of consumables and systems sold year over year. Gross margin as a percentage of revenue increased to 76% during the three months ended September 30, 2024, from 71% in the same period of 2023.

Revenues for the nine month-period ended September 30, 2024, were \$22.3 million compared to \$13.4 million for the same period of 2023, an increase of \$8.9 million, or 66%. The increase was primarily driven by the continued increased sales of our UltraMIST® system. The increase in revenues was due to an increase in the average selling price of our consumables and parts revenue year over year, and the remainder of the growth was related to an increase in the number of consumables and systems sold year over year. Gross margin as a percentage of revenue increased to 74% during the nine months ended September 30, 2024, from 71% in the same period of 2023.

General and Administrative Expenses

General and administrative expenses decreased \$0.1 million or 5% for the three months ended September 30, 2024, compared with the same period of 2023. The decrease for the three months ended September 30, 2024, was primarily due to a decrease in insurance and consulting costs. General and administrative expenses increased \$1.4 million, or 21%, for the nine months ended September 30, 2024, compared with the same period of 2023. The increase for the nine months ended September 30, 2024, was primarily due to severance costs, a non-recurring legal settlement, increased headcount expenses.

Selling and Marketing Expenses

Selling and marketing expenses increased by \$1.2 million, or 112%, for the three months ended September 30, 2024, as compared with the same period of 2023. The increase was primarily due to increased head count and commission expenses as the sales team and activity grew in comparison to the same period of 2023. Selling and marketing expenses increased by \$1.0 million, or 30%, for the nine months ended September 30, 2024, as compared with the same period of 2023. The increase was primarily due to increased head count and commission expenses as the sales team and activity grew in comparison to the same period of 2023.

Research and Development Expenses

Research and development expenses decreased slightly for the three months ended September 30, 2024, as compared with the same period of 2023. Research and development expenses as a percentage of revenue decreased to 1.7% during the three months ended September 30, 2024, compared to 3.3% for the same period in 2023. Research and development expenses increased \$83,000, or 19%, for the nine months ended September 30, 2024, as compared with the same period of 2023. Research and development expenses as a percentage of revenue decreased to 2.3% during the nine months ended September 30, 2024, compared to 3.2% for the same period in 2023.

Other (Expense)/Income, net

(in thousands)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Interest expense	\$ (3,661)	\$ (3,845)	\$ 184	5%	\$ (11,004)	\$ (12,504)	\$ 1,500	12%
Gain on extinguishment of debt	-	-	-	nm	5,205	-	5,205	nm
Change in fair value of derivatives	(18,849)	(19,325)	476	2%	(17,633)	(29,943)	12,310	41%
Other (expense) income	(100)	1	(101)	nm	1,913	(16)	1,929	nm
Other (expense), net	<u>\$ (22,610)</u>	<u>\$ (23,169)</u>	<u>\$ 559</u>	<u>2%</u>	<u>\$ (21,519)</u>	<u>\$ (42,463)</u>	<u>\$ 20,944</u>	<u>49%</u>

nm - not meaningful

Other expense decreased by \$0.6 million to \$22.6 million for the three months ended September 30, 2024, as compared to the same period for 2023. The change was primarily due to a decrease in change in fair value of derivatives expense of \$0.5 million.

Other expense decreased by \$20.9 million to \$21.5 million for the nine months ended September 30, 2024, as compared to the same period for 2023. The decrease was primarily due to a decrease in change in fair value of derivatives expense of \$12.3 million, recognition of a non-recurring gain on extinguishment of debt of \$5.3 million and the receipt of \$2.5 million from a third-party license and option agreement.

Liquidity and Capital Resources

Since inception, we have incurred losses from operations each year. As of September 30, 2024, we had an accumulated deficit of \$239 million. Historically, our operations have primarily been funded from the sale of capital stock, notes payable, and convertible debt securities. The events of default on our senior secured debt and working capital deficit have raised substantial doubt as to our ability to continue as a going concern for a period of at least twelve months from the filing of this Form 10-Q. We expect to devote substantial resources for the commercialization of the UltraMIST and PACE systems which will require additional capital resources to remain a going concern.

Management's plans may include obtaining additional capital in 2024. We could obtain additional capital through the conversion of outstanding warrants, issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders. In addition, there can be no assurances that our plans to obtain additional capital will be successful on the terms or timeline we expect, or at all. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or, if available, obtain funds through financing transactions with unfavorable terms.

Statement of Cash Flows

(in thousands)	For the nine months ended September 30,	
	2024	2023
Cash flows provided by (used in) operating activities	\$ 1,714	\$ (3,253)
Cash flows used in investing activities	\$ (254)	\$ (156)
Cash flows provided by (used in) financing activities	\$ (119)	\$ 3,356

Cash provided by operating activities during the nine months ended September 30, 2024, totaled \$1.7 million as compared to cash used by operating activities of \$3.3 million in the previous year period. This improvement in cash provided by operations was primarily driven by the receipt of \$2.5 million related to a license agreement and option agreement, the increase in revenues, and improvements in operations management including accounts receivable, inventory and accounts payable.

Critical Accounting Estimates

We have used various accounting policies to prepare the condensed consolidated financial statements in accordance with U.S. GAAP. Our significant accounting policies are disclosed in Note 3 to the consolidated financial statements in Part II Item 8. "Financial Statements and Supplementary Data" in our Annual Report on Form 10-K filed with the SEC on March 21, 2024.

The preparation of the condensed consolidated financial statements, in conformity with U.S. GAAP, requires us to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses. These estimates reflect our best judgment about economic and market conditions and the potential effects on the valuation and/or carrying value of assets and liabilities based upon relevant information available. We base our estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

The following accounting estimates are deemed critical:

Litigation Contingencies

We may be involved in legal actions involving product liability, intellectual property and commercial disputes, tax disputes, and governmental proceedings and investigations. The outcomes of these legal actions are not completely within our control and may not be known for prolonged periods of time. In some actions, the enforcement agencies or private claimants seek damages that could require significant expenditures or result in lost revenues or limit our ability to conduct business in the applicable jurisdictions. Estimating probable losses from our litigation and governmental proceedings is inherently difficult, particularly when the matters are in early procedural stages, with incomplete scientific facts or legal discovery; involve unsubstantiated or indeterminate claims for damages; potentially involve penalties, fines, or punitive damages; or could result in a change in business practice. The Company records a liability in the condensed consolidated financial statements for loss contingencies when a loss is known or considered probable, and the amount may be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed. Our significant legal proceedings are discussed in Note 13 to the condensed consolidated financial statements.

Derivative Liabilities from Embedded Conversion Options and Warrants

The Company classified certain convertible instruments as having embedded conversion options which qualified as derivative financial instruments to be separately accounted for. The Company also further determined that certain warrants also qualified as derivative financial instruments. Various valuation models were used to estimate the fair value of these derivative financial instruments that are classified as derivative liabilities on the condensed consolidated balance sheets. The models include subjective input assumptions that can materially affect the fair value estimates and as such are subject to uncertainty. Our significant input assumptions are discussed in Note 10 to the condensed consolidated financial statements.

Segment and Geographic Information

We have determined that we have one operating segment. Our revenues are generated from sales primarily in the United States. International sales include sales in Europe, Canada, the Middle East, Central America, South America, Asia, and Asia/Pacific. All significant expenses are generated in the United States and all significant assets are in the United States.

Effects of Inflation

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide the information required under this item.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2024. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not operating effectively as of September 30, 2024. Our disclosure controls and procedures were not effective because of the “material weakness” described below.

We had identified three material weaknesses in internal control over financial reporting from prior periods that remain unremediated. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis. Because the items described below could have resulted in material misstatement of our annual or interim financial statements, we determined each constitutes a material weakness.

As of September 30, 2024, the Company has still identified the following material weaknesses:

1. The Company lacked expertise and resources to analyze and properly apply U.S. GAAP to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distributing agreements with select vendors.
2. The Company lacked internal resources to analyze and properly apply U.S. GAAP to accounting for financial instruments included in service agreements with select vendors.
3. The Company has failed to implement controls around the following accounting processes: Equity, Financial Reporting, Accounts Payable, Expenses, Revenue, Accounts Receivable, Tax, Cash, Debt, Fixed Assets, Inventory, Commissions, Entity-Level, Human Resources/Payroll, and IT processes: change management, operations, access security. As such, we believe that accounting and IT processes and procedures need to be tested for operating effectiveness.

As a result, management concluded that its internal control over reporting was not effective as of September 30, 2024.

Remediation Plan

Management is fully committed to addressing the material weaknesses in our internal controls and has implemented several key initiatives to strengthen them. To that end, the Company has continued to implement and enhance appropriate internal controls and contracted with CliftonLarsonAllen, LLP starting in the third quarter 2023 to conduct a valuation engagement. This engagement aims to provide an estimated conclusion of value and a summary, restricted appraisal report to assist management in determining the fair value of warrants to purchase the Company's stock, embedded derivatives, and other interests.

Additionally, we engaged a third-party consultant to help design and document our internal controls and conduct a thorough risk assessment of our financial reporting processes. We plan to remediate and implement these controls for high-risk processes throughout 2024. We have also hired a highly experienced Director of Internal Audit to review, adjust, as needed, and test our internal controls and ensure they function as intended. We recently acquired GRC (Governance, Risk, and Compliance) software from Workiva to support these efforts. Furthermore, we plan to hire additional personnel and segregate certain duties to enhance our control activities and effectively mitigate risks. Until we fully remediate the material weaknesses, we will perform additional analyses and procedures to ensure our consolidated financial statements comply with U.S. GAAP. We remain vigilant in identifying any additional material weaknesses that may arise and are prepared to adjust our remediation strategies as needed.

We are collaborating with an external vendor to enhance our IT general controls over our enterprise resource planning system. This initiative aims to establish a robust framework for executing IT general controls, addressing weaknesses in our internal controls, and providing a solid framework for future testing.

The existence of any material weakness or significant deficiency requires management to devote significant time and incur significant expense to remediate any such material weaknesses or significant deficiencies, and management may not be able to remediate any such material weaknesses or significant deficiencies in a timely manner. The existence of any material weakness in our internal control over financial reporting could also result in errors in our financial statements that could require us to restate our financial statements, cause us to fail to meet our reporting obligations, and cause shareholders to lose confidence in our reported financial information, all of which could materially and adversely affect our business and stock price.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2024, that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting, except as disclosed in "Remediation Plan" above.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS.

For information regarding legal proceedings at September 30, 2024, see Note 14 to the condensed consolidated financial statements, which information is incorporated herein by reference.

Item 1A. RISK FACTORS.

There have been no material changes from our risk factors as previously reported in Part I, Item 1A "Risk Factors" in our 2023 Annual Report.

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

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

Item 5. OTHER INFORMATION.

During the three months ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any non-Rule 10b5-1 trading arrangement (as defined in the SEC's rules).

Item 6. EXHIBITS

[2.1](#) Agreement and Plan of Merger, dated as of August 23, 2023, by and among SEP Acquisition Corp., SEP Acquisition Holdings Inc., and SANUWAVE Health, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on August 23, 2023).

[2.2](#) Amendment Number one to Agreement and Plan of Merger, dated February 27, 2024, by and between SEP Acquisition Corp. and Sanuwave Health, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on February 28, 2024).

[2.3](#) Amendment Number Two to Agreement and Plan of Merger, dated as of April 25, 2024, by and between SEP Acquisition Corp. and Sanuwave Health, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on April 26, 2024).

[2.4](#) Amendment Number Three to Agreement and Plan of Merger, dated as of May 28, 2024, by and between SEP Acquisition Corp. and Sanuwave Health, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on May 28, 2024).

[3.1](#) Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Form 10-SB filed with the SEC on December 18, 2007).

[3.2](#) Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).

[3.3](#) Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Exhibit A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).

[3.4](#) Bylaws (Incorporated by reference to Exhibit 3.02 to the Form 10-SB filed with the SEC on December 18, 2007).

[3.5](#) Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on March 18, 2014).

[3.6](#) Certificate of Amendment to the Articles of Incorporation, dated September 8, 2015 (Incorporated by reference to Exhibit 3.6 to the Form 10-K filed with the SEC on March 30, 2016).

[3.7](#) Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock of the Company dated January 12, 2016 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on January 19, 2016).

3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock of the Company dated January 31, 2020 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on February 6, 2020).
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock of the Company dated January 31, 2020 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on February 6, 2020).
3.10	Certificate of Designation of Series D Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on May 20, 2020).
3.11	Certificate of Amendment of the Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on January 5, 2021).
3.12	Certificate of Amendment of the Articles of Incorporation, dated January 31, 2023 (Incorporated by reference to Exhibit 3.12 to the Form S-1/A filed with the SEC on January 31, 2023).
4.1	Form of Future Advance Convertible Promissory Note issued to certain purchasers, dated January 21, 2024 (Incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the SEC on January 25, 2024).
4.2	Forms of Common Stock Purchase Warrants issued to certain purchasers, dated January 21, 2024 (Incorporated by reference to Exhibit 4.2 to the Form 8-K filed with the SEC on January 25, 2024).
10.1	Securities Purchase Agreement, dated January 21, 2024, by and among the Company and the purchasers identified on the signature pages thereto (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on January 25, 2024).
10.2	Security Agreement, dated January 21, 2024, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on January 25, 2024).
10.3	Subordination Agreement, dated January 21, 2024, by and among the Company, NH Expansion Credit Fund Holdings LP and certain creditors (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on January 25, 2024).
10.4	Registration Rights Agreement, dated January 21, 2024, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on January 25, 2024).
10.5	Form of waiver letter with purchasers in January 2024 offering (Incorporated by reference to Exhibit 10.5 to the Form 8-K filed with the SEC on January 25, 2024).
10.6	Form of letter agreement with purchasers in January 2024 offering (Incorporated by reference to Exhibit 10.6 to the Form 8-K filed with the SEC on January 25, 2024).
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 Principal Executive Officer.
32.2*	Section 1350 Certification of the Chief Financial Officer.
101.INS*	XBRL Instance.
101.SCH*	XBRL Taxonomy Extension Schema.
101.CAL*	XBRL Taxonomy Extension Calculation.

[101.DEF*](#) XBRL Taxonomy Extension Definition.

[101.LAB*](#) XBRL Taxonomy Extension Labels.

[101.PRE*](#) XBRL Taxonomy Extension Presentation.

[104](#) Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

*** Filed herewith.**

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.

SANUWAVE HEALTH, INC.

Dated: November 7, 2024

By: /s/ Morgan Frank

Morgan Frank
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

Dated: November 7, 2024

By: /s/ Peter Sorensen

Peter Sorensen
Chief Financial Officer
(Principal Financial and Accounting Officer)