

**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 June 30, 2025

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

For the transition period from _____ to _____

Commission File Number 000-52985

SANUWAVE Health, Inc.

(Exact name of registrant as specified in its charter)

Nevada **20-1176000**

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

11495 Valley View Road
Eden Prairie, MN **55344**

(Address of principal executive offices) (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
Common Stock, par value \$0.001 per share	SNWV	The Nasdaq Stock Market LLC

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, a 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 ☐ Accelerated filer ☐
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 August 4, 2025, there were issued and outstanding 8,568,005 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: results of operations, liquidity, and operations, restrictions and new regulations on our operations and processes; 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, 2024, filed on March 20, 2025. 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 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, 2024, filed on March 20, 2025.

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)

	June 30, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,496	\$ 10,237
Accounts receivable, net of allowance of \$1,278 and \$1,147, respectively	3,848	3,329
Inventory	5,911	4,149
Prepaid expenses and other current assets	1,913	682
Total Current Assets	20,168	18,397
Non-Current Assets:		
Property and equipment, net	1,587	303
Right of use assets, net	653	429
Intangible assets, net	3,378	3,730
Goodwill	7,260	7,260
Total Non-current Assets	12,878	11,722
Total Assets	\$ 33,046	\$ 30,119
LIABILITIES		
Current Liabilities:		
Senior secured debt	\$ 26,774	\$ 25,305
Accounts payable	4,002	3,728
Accrued expenses	3,289	4,678
Warrant liability	12,018	8,107
Current portion of operating lease liabilities	82	126
Current portion of finance lease liabilities	115	175
Current portion of contract liabilities	221	193
Other	-	33
Total Current Liabilities	46,501	42,345
Non-current Liabilities:		
Operating lease liabilities, less current portion, net of incentives	974	125
Finance lease liabilities, less current portion	11	66
Contract liabilities, less current portion	301	300
Other	34	-
Total Non-current Liabilities	1,320	491
Total Liabilities	\$ 47,821	\$ 42,836
Commitments and Contingencies (Footnote 17)		
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 designated, respectively; no shares issued and outstanding at June 30, 2025 and December 31, 2024		
	\$ -	\$ -
Common stock, par value \$0.001, 2,500,000,000 shares authorized; 8,568,005 and 8,543,686 issued and outstanding at June 30, 2025 and December 31, 2024, respectively *		
	9	9
Additional paid-in capital	241,248	238,685
Accumulated deficit	(256,042)	(251,421)
Accumulated other comprehensive loss	10	10
Total Stockholders' Deficit	(14,775)	(12,717)
Total Liabilities and Stockholders' Deficit	\$ 33,046	\$ 30,119

* 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 INCOME (LOSS)
(UNAUDITED)
(In thousands, except share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	\$ 10,164	\$ 7,162	\$ 19,506	\$ 12,948
Cost of Revenues	2,206	1,922	4,164	3,506
Gross Margin	7,958	5,240	15,342	9,442
Operating Expenses:				
General and administrative	4,039	1,839	8,506	5,514
Selling and marketing	1,674	1,034	3,205	2,266
Research and development	194	195	402	358
Depreciation and amortization	174	180	366	362
Total Operating Expenses	6,081	3,248	12,479	8,500
Operating Income	1,877	1,992	2,863	942
Other Income (Expense):				
Interest expense	(1,874)	(3,396)	(3,726)	(6,633)
Interest expense, related party	-	(387)	—	(710)
Gain on extinguishment of debt	-	5,310	—	5,205
Change in fair value of derivative liabilities	990	3,717	(3,911)	1,216
Other expense	(27)	(685)	(28)	(787)
Other income	89	10	181	2,800
Total Other Income (Expense)	(822)	4,569	(7,484)	1,091
Net Income (Loss)	\$ 1,055	\$ 6,561	\$ (4,621)	\$ 2,033
Other Comprehensive Income (Loss)				
Foreign currency translation adjustments	-	10	-	121
Total Comprehensive Income (Loss)	\$ 1,055	\$ 6,571	\$ (4,621)	\$ 2,154
Earnings (Loss) per Share:				
Basic *	\$ 0.12	\$ 2.08	\$ (0.54)	\$ 0.65
Diluted *	\$ 0.01	\$ 1.77	\$ (0.54)	\$ 0.55
Weighted average shares outstanding				
Basic *	8,561,737	3,152,595	8,554,706	3,126,000
Diluted *	9,167,846	3,699,501	8,554,706	3,663,730

* 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 June 30, 2025

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Number of Shares Issued and Outstanding	Par Value				
Balances as of March 31, 2025	8,548,473	\$ 9	\$ 239,786	\$ (257,097)	\$ 10	\$ (17,292)
Stock-based compensation	-	-	1,132	-	-	1,132
Stock options exercised	17,008	-	253	-	-	253
Shares granted in lieu of board of director fees	2,524	-	77	-	-	77
Foreign currency translation adjustment	-	-	-	-	-	-
Net income	-	-	-	1,055	-	1,055
Balances as of June 30, 2025	8,568,005	\$ 9	\$ 241,248	\$ (256,042)	\$ 10	\$ (14,775)

Three Months Ended June 30, 2024

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Number of Shares Issued and Outstanding	Par Value				
Balances as of March 31, 2024	3,041,492	\$ 3	\$ 176,979	\$ (224,577)	\$ -	\$ (47,595)
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	-	-	-	-	10	10
Net income	-	-	-	6,561	-	6,561
Balances as of June 30, 2024	3,150,062	\$ 3	\$ 178,397	\$ (218,016)	\$ 10	\$ (39,606)

* 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)

Six Months Ended June 30, 2025

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Number of Shares Issued and Outstanding	Par Value				
Balances as of December 31, 2024	8,543,686	\$ 9	\$ 238,685	\$ (251,421)	\$ 10	\$ (12,717)
Stock-based compensation	4,787	-	2,233	-	-	2,233
Stock options exercised	17,008	-	253	-	-	253
Shares granted in lieu of board of director fees	2,524	-	77	-	-	77
Net loss	-	-	-	(4,621)	-	(4,621)
Balances as of June 30, 2025	8,568,005	\$ 9	\$ 241,248	\$ (256,042)	\$ 10	\$ (14,775)

Six Months Ended June 30, 2024

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Number of Shares Issued and Outstanding	Par Value				
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 income	-	-	-	2,033	-	2,033
Balances as of June 30, 2024	3,150,062	\$ 3	\$ 178,397	\$ (218,016)	\$ 10	\$ (39,606)

* 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)	Six Months Ended June 30,	
	2025	2024
Cash Flows - Operating Activities:		
Net income (loss)	\$ (4,621)	\$ 2,033
Adjustments to reconcile net income to net cash (used in) provided by operating activities		
Stock-based compensation	2,106	-
Depreciation and amortization	388	393
Amortization of right-of-use assets	185	87
Reserve for credit losses	131	99
Gain on extinguishment of debt	-	(5,205)
Change in fair value of derivative liabilities	3,911	(1,216)
Amortization of debt issuance and debt discounts	1,062	3,274
Accrued interest and accrued interest, related party	-	1,859
Proceeds from tenant improvement funds	429	-
Changes in operating assets and liabilities		
Accounts receivable	(650)	(340)
Inventory	(1,762)	220
Prepaid expenses and other assets	(1,231)	118
Accounts payable	274	(1,259)
Accrued expenses and contract liabilities	(746)	369
Net Cash Flows (Used in) Provided by Operating Activities	(524)	432
Cash Flows - Investing Activities		
Purchase of property and equipment	(1,321)	(206)
Net Cash Flows Used in Investing Activities	(1,321)	(206)
Cash Flows - Financing Activities		
Proceeds from exercises of stock options	253	-
Payment of note payable	-	(2,175)
Proceeds from convertible notes payable	-	1,300
Proceeds from promissory note payable, related party	-	500
Proceeds from factoring, net	-	831
Payments of principal on finance leases	(149)	(140)
Net Cash Flows Provided by Financing Activities	104	316
Effect of Exchange Rates on Cash	-	121
Net Change in Cash During Period	(1,741)	663
Cash at Beginning of Period	10,237	1,797
Cash at End of Period	\$ 8,496	\$ 2,460

Supplemental Information:

Cash paid for interest	\$ 2,255	\$ 2,055
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Non-cash Investing and Financing Activities:

Capitalize interest into senior secured debt	407	3,850
Shares granted in lieu of board of director fees	77	-
Stock options granted in lieu of cash bonus	117	-
Right-of-use assets obtained in exchange for lease liabilities	430	-
RSUs granted in exchange for services	10	-
Warrants issued in conjunction with convertible promissory notes	-	3,633
Conversion of asset-backed secured promissory notes to convertible promissory notes	-	4,584
Shares issued for settlement of debt	-	1,412
Write off deferred merger costs	-	1,226

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
June 30, 2025

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 regenerative medicine utilizing noninvasive ultrasound or shockwaves to produce a biological response promoting the repair and regeneration of tissue, musculoskeletal, 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 June 30, 2025, and for the three and six months ended June 30, 2025, and 2024 is unaudited; however, in the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2025, are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2025.

The condensed consolidated balance sheet on December 31, 2024, 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 condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on March 20, 2025 (the "2024 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 condensed consolidated 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 as a result of the Reverse Stock Split, and no fractional shares were issued as a result of the Reverse Stock Split. Any fractional shares that would have resulted from the Reverse Stock Split were settled in cash. The Reverse Stock Split affected all common stockholders uniformly and did not alter any stockholder's percentage interest in the Company's common stock, except to the extent that the Reverse Stock Split resulted in certain stockholders experiencing an adjustment of a fractional share as described above.

Reclassification - Certain accounts in the prior period condensed consolidated balance sheets and statement of cash flows have been reclassified to conform to the presentation of the current period condensed consolidated financial statements. These reclassifications had no effect on the previously reported operating results.

2. Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has an accumulated deficit, has negative working capital, and its Senior Secured Note becomes due in September 2025, which raises substantial doubt as to its ability to continue as a going concern for a period of 12 months from the filing of this Form 10-Q.

During the three and six months ended June 30, 2025, and prior fiscal year ended December 31, 2024, the Company achieved operating income. This is attributable to the implementation and execution of several strategic initiatives, primarily revenue growth initiatives and a capital raise from a private placement in October 2024, which have positively impacted the Company's operations.

Despite the positive operating income in the current year, the Company continues to monitor its financial position closely.

In addition to the operational improvements, the Company is addressing its financial obligations, including the significant portion of debt that matures in September 2025. Management is actively engaged in discussions with lenders and financial

institutions to refinance this debt, which could extend the maturity of the debt and provide additional liquidity to support ongoing operations and strategic initiatives.

Management acknowledges that it must continue to execute its strategic initiatives effectively to ensure long-term financial stability, and that failure to do so could have a material adverse effect on the Company.

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. Our 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 we 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 2024 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, stock-based compensation, incremental borrowing rate, and the estimated fair value of financial instruments, including warrants.

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 standalone 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.

Licensing Fees - Licensing transactions include distribution licenses and intellectual property licenses. Licensing revenue is recognized as the Company satisfies its performance obligations, which may vary with the terms of the licensing agreement.

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.

Stock-based compensation - The Company accounts for stock-based compensation in accordance with ASC Topic 718, “Compensation—Stock Compensation”. Stock-based compensation expense is recognized for all share-based payment awards based on the grant-date fair value. The Company grants the following types of equity awards:

Time-based or service awards, which vest based on continued service over a specified period. These awards are valued using the Black-Scholes option pricing model (for stock options) or the grant-date fair value of the underlying common stock (for restricted stock units).

Performance-based awards, which vest upon the achievement of pre-established internal performance targets. These awards are valued using the Black-Scholes option pricing model.

Market-based awards, which vest upon the attainment of defined market conditions, such as stock price milestones. These awards are valued using a Monte Carlo simulation model.

The Company recognizes stock-based compensation expense on a straight-line basis over the requisite service period for time-based awards, on a straight-line basis over the requisite service period for performance-based awards when it is probable that the associated performance condition will be satisfied, and on a straight-line basis over the requisite service period for market-based awards irrespective of likelihood that the associated market condition will be satisfied. Forfeitures are recognized as they occur. Compensation expense is included in the same functional expense categories as the related employee payroll costs.

Leases

The Company accounts for leases in accordance with ASC Topic 842, "Leases". At the commencement date of a lease, the Company recognizes a right-of-use ("ROU") asset and a lease liability for all leases with a term greater than 12 months. Short-term leases (those with an original term of 12 months or less) are not recorded on the balance sheet; lease expense for these is recognized on a straight-line basis over the lease term.

Lease liabilities are measured at the present value of future lease payments using the Company's incremental borrowing rate unless the implicit rate is readily determinable. ROU assets are measured at the initial lease liability, adjusted for lease incentives, initial direct costs, and any prepaid or accrued lease payments.

Lease Incentives

Lease incentives received from lessors, such as rent-free periods or reimbursement for leasehold improvements, are recognized as a reduction to the ROU asset at lease commencement. These incentives are amortized on a straight-line basis over the lease term, consistent with the amortization of the ROU asset. Incentives that are paid directly to the Company or on its behalf are included in the measurement of the ROU asset and reduce the total lease cost recognized over the lease term.

New accounting pronouncements

ASU 2024-03, Disaggregation of Income Statement Expenses

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-03, Income Statement - Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures to improve the disclosures about a public entity's expenses and provide more detailed information about the types of expenses in commonly presented expense captions such as inventory purchases, employee compensation, depreciation and intangible asset amortization. The disclosure requirements must be applied retrospectively to all prior periods presented in the financial statements. The effective date for the standard is for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

Recently adopted accounting pronouncements

ASU 2023-09, Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 aims to enhance the transparency and decision usefulness of income tax disclosures. ASU 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). ASU 2023-09

also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-09 prospectively in the first quarter of 2025. The adoption of ASU 2023-09 did not have a material impact on the Company's financial position or results of operations.

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. Allowance for Credit Losses

The Company maintains an allowance for credit losses to cover estimated losses on accounts receivable. The allowance is based on the Company's assessment of various factors, including historical loss experience, the age of receivables, current economic conditions, and the creditworthiness of customers. The allowance for credit losses is reviewed and adjusted as necessary at each reporting date.

The roll-forward of the allowance for credit losses is as follows:

(in thousands)	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024
Allowance for credit losses, December 31	\$ 1,147	\$ 1,237
Provision for credit losses	136	113
Write-offs	(5)	(156)
Allowance for credit losses, June 30	<u>\$ 1,278</u>	<u>\$ 1,194</u>

6. Inventory

Inventory consisted of the following:

(in thousands)	June 30, 2025	December 31, 2024
Finished goods	\$ 3,202	\$ 386
Parts and accessories	2,709	3,763
Total Inventory	<u>\$ 5,911</u>	<u>\$ 4,149</u>

7. Leases

Operating lease commitments - On March 27, 2025, the Company entered into a new operating lease agreement for its new headquarters in Eden Prairie, Minnesota. The lease term commenced on March 28, 2025, and extends for a period of 5.5 years, expiring on August 30, 2030. The lease includes an option to renew for an additional 5 years at the Company's discretion.

Lease payments - Under the terms of the lease, the Company is obligated to make monthly lease payments starting September 1, 2025, with an annual escalation of 3.5% starting on September 1, 2026 through August 30, 2030. The total minimum lease payments over the initial lease term amount to approximately \$1.4 million.

Right-of-use asset and lease liability - In accordance with ASC 842, "Leases," the Company recognized a right-of-use asset and a corresponding lease liability on the condensed consolidated balance sheets as of March 28, 2025. The initial

measurement of the right-of-use asset and lease liability was \$0.4 million, which represents the present value of the lease payments over the lease term, discounted at the Company's incremental borrowing rate of 11.5%.

Lease-incentive - As part of a new office lease agreement, the Company is entitled to receive reimbursement payments from the lessor as a lease incentive. These payments, totaling \$586 thousand, are intended to offset certain costs associated with leasehold improvements.

Under ASC 842, lease incentives are accounted for as a reduction of the right-of-use asset and recognized over the lease term. As of June 30, 2025, the Company recorded a short-term lease liability debit balance of \$54 thousand for the new office lease, reflecting future reimbursements from the lessor. This balance is classified net with long-term lease liabilities on the condensed consolidated balance sheet and will be amortized as a reduction to lease expense over the remaining lease term.

Lease expense - For the three and six months ended June 30, 2025, the Company recognized lease expense of \$37 thousand and \$49 thousand, respectively, related to this operating lease, which is included in general and administrative expenses in the condensed consolidated statements of comprehensive income (loss).

As of June 30, 2025, the maturities of the Company's operating leases, which have initial or remaining lease terms more than one year, consist of the following:

(in thousands)	Operating Leases
2025	\$ (13)
2026	345
2027	328
2028	282
2029	292
Thereafter	199
Total Lease Payments	<u>1,433</u>
Imputed interest	(377)
Present value of lease liabilities	<u><u>\$ 1,056</u></u>

The weighted-average useful life of operating leases at June 30, 2025, is 4.65 years.

The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

8. Senior Secured Debt

The following table summarizes outstanding senior secured debt:

(in thousands)	June 30, 2025			December 31, 2024		
	Principal	Debt Discount	Carrying Value	Principal	Debt Discount	Carrying Value
Senior secured debt	\$ 27,305	\$ (531)	\$ 26,774	\$ 26,898	\$ (1,593)	\$ 25,305

Senior secured promissory note payable ("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%, paid quarterly. 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 June 2022, the Company entered into the Third Amendment to the Note and Warrant Purchase and Security Agreement (the “Third NWPSA”). The Third NWPSA provided for (i) the extension of the agent’s and holder’s forbearance of exercising its remedies arising from Existing Defaults (as defined in the NWPSA) to the earlier of (x) the occurrence of an Event of Default (as defined in the NWPSA) or (y) August 30, 2022, and (ii) the extension to file a registration statement with the Securities and Exchange Commission to register the resale of the Advisor Shares (as defined in the NWPSA) no later than August 30, 2022.

In June 2023, the Company entered into a Fourth Amendment to the NWPSA, which provided the Company an extension of the holder forbearing from exercising the remedies arising from the existing defaults to the earlier of the occurrence of an event of default and December 31, 2024. The amendment also added a consent fee of 2% of the original principal amount of the NWPSA, payable in cash at maturity, accounted for as additional debt issuance costs. The amendment also deferred interest that would otherwise have been due on June 30, 2023, and September 30, 2023. The interest was instead compounded and added to the principal amount of the notes and bear interest at a rate of 20.25% per annum. The amendment also required the Company to complete an equity financing that resulted in gross cash proceeds of at least \$2.5 million by July 15, 2023. This financing successfully closed on July 21, 2023.

In March 2024, the Company entered into a Consent, Limited Waiver and Fifth Amendment to Note and Warrant Purchase Agreement (the “Fifth Amendment”). The Fifth Amendment provided (i) consent to enter into a License and Option Agreement and consummation of the License and Option Transaction (ii) provided 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 provided 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 and (y) April 30, 2024. During the forbearance period, the outstanding obligations under the NWPSA continued to accrue interest at the default rate.

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 provided 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 accrued interest at the default rate.

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 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 consented 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; gross proceeds from the sale of common stock of at least \$9.0 million in a private placement (for further details on this private placement transaction, see Note 16 on the 2024 Annual Report) and the Reverse Stock Split if the Company had 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 of the Company’s common stock following the Reverse Stock Split.

As of June 30, 2025, the Company is in compliance with all covenants in the Senior Secured Note.

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.

(In millions)	Three Months Ended		Six Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
Amortization of debt issuance costs and debt discount, included in interest expense	\$ 0.6	\$ 2.1	\$ 1.1	\$ 4.0
Interest expense	\$ 1.9	\$ 1.4	\$ 3.7	\$ 3.1

9. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	June 30, 2025	December 31, 2024
Registration penalties	\$ 1,583	\$ 1,583
Board of directors fees	172	249
Employee compensation	906	2,232
Other	628	614
Accrued expenses	\$ 3,289	\$ 4,678

10. Fair Value Measurements

The Company uses various inputs to measure the outstanding warrants 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:

(in thousands)	Fair value measured at June 30, 2025			
	Fair value at June 30, 2025	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 12,018	\$ -	\$ -	\$ 12,018

(in thousands)	Fair value measured at December 31, 2024			
	Fair value at December 31, 2024	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 8,107	\$ -	\$ -	\$ 8,107

There were no transfers among Levels 1, 2 or 3 during the three and six months ended June 30, 2025, and 2024. 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 and unobservable inputs.

Warrant Liability

The Company's liability classified warrants as of June 30, 2025, and December 31, 2024, were valued using the Black Scholes valuation model.

Significant Black Scholes valuation model inputs related to the Company's warrants are listed below:

	June 30, 2025	December 31, 2024
Weighted average expected life in years	0.35	0.85
Weighted average volatility	72%	91%
Value of underlying shares	\$32.86	\$22.76
Weighted average risk free interest rate	4.27%	4.10%
Expected dividend yield	0%	0%

A summary of the Level 3 warrant activity for the three and six months ended June 30, 2025, is as follows:

(in thousands, except per share data)	Warrants Outstanding	Fair Value per Share	Warrant Liability Fair Value
Balance at March 31, 2025	390	\$ 33.35	\$ 13,008
Change in fair value	-		(990)
Balance at June 30, 2025	390	\$ 30.82	\$ 12,018

(in thousands, except per share data)	Warrants Outstanding	Fair Value per Share	Warrant Liability Fair Value
Balance at December 31, 2024	390	\$ 20.79	\$ 8,107
Change in fair value	-		3,911
Balance at June 30, 2025	390	\$ 30.82	\$ 12,018

11. Promissory Notes Payable

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 \$16.2 million in August 2022, \$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, 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 six months ended June 30, 2025 totaled \$0, and interest expense for the three and six months ended June 30, 2024, totaled \$1.2 and \$2.8 million, respectively.

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 was subject to adjustment, including if the Company issued or sold shares of common stock for a price per share less than the Conversion Price of the Notes or if the Company listed 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 was less than \$15.00 per share; provided, however, that the Conversion Price was never less than \$3.75. The Notes contained customary events of default and covenants, including limitations on incurrences of indebtedness and liens. The Notes had a term of 12 months from the date of issue.

In May 2024, the Company utilized its election to convert the May 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 94,126 shares of common stock.

All remaining outstanding convertible notes payable and convertible notes payable related party converted on October 18, 2024 to 591,802 shares of common stock. The outstanding principal and interest converted totaled \$8.9 million. The Company recognized a \$0.3 million gain on conversion of the Notes.

Promissory note payable, related parties - In June 2024 the Company entered into a \$0.5 million promissory note with a related party. Interest was accrued at 12% with an original maturity date of December 3, 2024. The Note was paid in full with accrued interest in October 2024.

Acquisition Convertible promissory notes payable - In August 2020, the Company entered into an asset purchase agreement with Celularity to acquire Celularity’s UltraMIST assets. A portion of the aggregate consideration of \$24 million paid for the assets included the issuance of a promissory note to Celularity in the principal amount of \$4 million (the “Seller Note”). The Seller Note matured on August 6, 2021, and was not repaid. The Company’s failure to pay the outstanding principal balance when due constituted an event of default under the terms of the Seller Note and, accordingly, it began accruing additional interest of 5.0% in addition to the 12.0% initial rate, as of the date of the default. As of December 31, 2024, the Seller Note had outstanding accrued interest of \$0. This Seller Note was settled in 2024 for a cash payment of \$2.2 million.

Convertible promissory notes payable, related party - In August 2020, the Company issued a convertible promissory note payable in the amount of \$1.4 million. The note matured on August 6, 2021, and was not repaid and thus was in default. As of December 31, 2024, the note had outstanding accrued interest of \$0.

The convertible promissory note was settled in 2024 for a cash payment of \$1.4 million, which resulted in a gain on the extinguishment of debt of \$0.8 million and a reduction in accrued interest of \$0.8 million.

12. Revenue

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

	Three Months Ended June 30, 2025			Three Months Ended June 30, 2024		
	United States	International	Total	United States	International	Total
Consumables and parts revenue	\$ 6,686	\$ 6	\$ 6,692	\$ 4,920	\$ 31	\$ 4,951
System revenue	3,445	-	3,445	2,112	-	2,112
License fees and other	-	10	10	-	15	15
Product Revenue	\$ 10,131	\$ 16	\$ 10,147	\$ 7,032	\$ 46	\$ 7,078
Rental Income	17	-	17	84	-	84
Total Revenue	\$ 10,148	\$ 16	\$ 10,164	\$ 7,116	\$ 46	\$ 7,162

	Six Months Ended June 30, 2025			Six Months Ended June 30, 2024		
	United States	International	Total	United States	International	Total
Consumables and parts revenue	\$ 12,764	\$ 16	\$ 12,780	\$ 9,161	\$ 97	\$ 9,258
System revenue	6,643	-	6,643	3,413	71	3,484
License fees and other	-	15	15	-	20	20
Product Revenue	\$ 19,407	\$ 31	\$ 19,438	\$ 12,574	\$ 188	\$ 12,762
Rental Income	68	-	68	186	-	186
Total Revenue	\$ 19,475	\$ 31	\$ 19,506	\$ 12,760	\$ 188	\$ 12,948

13. Stock-Based Compensation

On August 7, 2024, the stockholders of the Company approved the 2024 Equity Incentive Plan (the “2024 Plan”). The 2024 Plan authorizes the issuance of up to 1,376,556 shares of common stock. Stock options granted under the 2024 Plan include service-based, performance-based, and market-based awards. Service-based stock options generally vest over a three-year period, expire 10 years from the date of grant, and are forfeited upon separation from the Company. Performance-based stock options vest upon the achievement of pre-established financial or operational performance criteria, as determined by the Company’s Board of Directors or Compensation Committee. These awards generally expire five years from the date of grant and are subject to forfeiture if the performance goals are not achieved within the specified performance period. Market-based stock options vest upon the attainment of certain market conditions, such as specified

stock price targets, and also expire five years after the grant date. The fair value of market-based awards is estimated using a Monte Carlo simulation model.

All awards under the 2024 Plan are subject to the terms and conditions of the 2024 Plan and the individual award agreements.

During the six months ended June 30, 2025, the Company granted performance- and market-based option awards to three employees which provide for the vesting of up to 65,500 shares of common stock. Vesting is contingent upon the achievement of specified performance or market conditions, with 100% of the related shares vesting upon satisfaction of each applicable condition.

The performance conditions include the achievement of (a) specific revenue recognized (12,750 shares), (b) specific adjusted Earnings Before Interest, Taxes, Depreciation and Amortization (“EBITDA”) targets (12,750 shares), (c) listing on NASDAQ (10,000 shares), (d) the refinancing or repayment of certain debt obligations (10,000 shares), and (e) various operations related milestones (10,000 shares). The market condition relates to the attainment of a defined stock price target (10,000 shares).

During the three months ended June 30, 2025, 5,500 shares subject to performance conditions (2,750 shares under criterion (a) and 2,750 shares under criterion (b)) were forfeited due to the termination of one of the employees. As a result, the maximum number of shares eligible to vest under these awards was reduced to 60,000 shares as of June 30, 2025.

As of June 30, 2025, the Company concluded that the performance conditions related to revenue, adjusted EBITDA, debt repayment, and the various operations related milestones were not probable of achievement, and accordingly, no compensation expense was recognized for those awards. The NASDAQ listing condition was achieved during the quarter ended March 31, 2025, and the related compensation expense was recognized in the quarter achieved.

The market condition has not been met as of June 30, 2025, however, compensation expense for the market-based award is recognized on a straight-line basis over the requisite service period, regardless of whether the market condition is ultimately satisfied. If the condition is achieved prior to the end of the service period, any unrecognized expense will be recognized immediately.

On November 1, 2010, the Company approved the Amended and Restated 2006 Stock Incentive Plan of SANUWAVE Health, Inc. effective as of January 1, 2010 (the “Stock Incentive Plan”). Upon the approval of the 2024 Plan by the Company's stockholders, no further awards will be made under the Stock Incentive Plan.

The Stock Incentive Plan permitted grants of awards to selected employees, directors, and advisors of the Company in the form of restricted stock or options to purchase shares of common stock. Options granted may include non-statutory options as well as qualified incentive stock options. The Stock Incentive Plan is administered by the board of directors of the Company. The Stock Incentive Plan gives broad powers to the board of directors of the Company to administer and interpret the form and conditions of each option.

The following table presents stock compensation expense recognized by the Company for the three and six months ended June 30, 2025. Total unrecognized compensation cost related to equity awards as of June 30, 2025 was \$9.9 million and is expected to be recognized over a weighted average period of 2.48 years. All stock compensation expense from the Stock Incentive Plan was recognized prior to 2024. The first grants from the 2024 Plan were issued in the three months ended December 31, 2024, thus there is no expense for the three and six months ended June 30, 2024. The Company recognizes compensation expense on a straight-line basis over the requisite service period, net of actual forfeitures.

	Three Months Ended June 30, 2025	Six Months Ended June 30, 2025
(in thousands)		
Cost of revenues	\$ 9	\$ 18
General and administrative	905	1,706
Selling and marketing	208	366
Research and development	10	26
Total expense	\$ 1,132	\$ 2,116

The following table presents a summary of stock options award activity during the six months ended June 30, 2025:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	1,137	\$ 15.97	9.5	\$ 9,305
Granted	342	28.75	6.8	1,411
Exercised	(17)	14.89	0.0	306
Forfeited	(153)	19.45	0.0	-
Outstanding, June 30, 2025	1,309	\$ 17.53	8.6	\$ 18,855
Exercisable, June 30, 2025	292	\$ 19.95	8.1	\$ 4,333

Valuation Information for Stock-Based Compensation

The fair value of each stock option award during the three and six months ended June 30, 2025 was based on the closing price of the Company's common stock on the date of the grant. Expected volatility was based on 100% of the historical realized volatilities of peer companies. The risk-free interest rate was based on the implied yield for U.S. Treasury zero-coupon issue with the remaining term equal to the expected term. The expected holding period was calculated using the simplified method. No dividend was assumed as the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. The Company's policy is to recognize forfeitures as they occur.

The weighted average assumptions used in the Black-Scholes option pricing model in valuing stock options granted in the three and six months ended June 30, 2025 are summarized in the table below:

	Three Months Ended June 30, 2025	Six Months Ended June 30, 2025
Fair value at grant date	\$30.19	\$29.00
Expected volatility	62%	62%
Risk-free interest rate	4%	4%
Expected holding period, in years	4.87	5.12
Dividend yield	0%	0%

14. Net Income (Loss) per Share

Basic net income (loss) per share is computed based on the weighted average number of shares outstanding during the applicable period, including nominally priced warrants. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding. Diluted net income (loss) per share is calculated based on the weighted average of shares of common stock outstanding and the number of additional shares that would have been outstanding if the potentially dilutive securities had been issued. The Company uses the treasury stock method to calculate the number of shares for the nominally priced warrants.

(in thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Numerator:				
Basic net income (loss) available to stockholders	1,055	6,561	(4,621)	2,033
Change in fair value of warrants	(990)	-	-	-
Diluted net income (loss) available to stockholders	65	6,561	(4,621)	2,033
Denominator:				
Weighted average common shares outstanding - Basic	8,562	3,153	8,555	3,126
Dilutive effect of warrants	363	-	-	-
Dilutive effect of stock options	243	-	-	-
Dilutive effect of convertible promissory notes including interest	-	547	-	538
Weighted average common shares outstanding - Diluted	9,168	3,700	8,555	3,664
Net income (loss) per share:				
Basic	\$ 0.12	\$ 2.08	\$ (0.54)	\$ 0.65
Diluted	\$ 0.01	\$ 1.77	\$ (0.54)	\$ 0.55

Diluted net income (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 that are nominally priced. In June 2024, the Company did not have any dilutive common stock equivalents that were nominally priced. The following securities were excluded from the calculation of diluted net loss per share during the six months ended June 30, 2025 because the result would have been anti-dilutive.

(in thousands)	Six Months Ended June 30,	
	2025	2024
Common stock options	102	42
Common stock purchase warrants	2	3,980
Convertible notes payable, including interest	-	55
	104	4,077

15. Concentration of Credit Risk and Limited Suppliers

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 six months ended June 30, 2025, and 2024 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Purchases:				
Vendor A	19%	32%	22%	20%
Vendor B	10%	-%	11%	-%

16. 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 three months ended March 31, 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.

17. Commitments and Contingencies

Litigation

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.

18. Segment Information

The Company operates in one reportable segment engaged in the design and sale of medical devices.

The accounting policies of the one reportable segment are the same as those described in the summary of significant accounting policies. The Chief Operating Decision Maker ("CODM") assesses performance for the reportable segment and decides how to allocate resources primarily based on gross profit that is also reported on the condensed consolidated statements of comprehensive income (loss). The measure of segment assets is reported on the condensed consolidated balance sheets as total assets.

The CODM uses gross profit to evaluate income (loss) generated from segment assets (return on assets) in deciding whether to reinvest profits or to apply them to other parts of the entity.

Net income (loss) is used to monitor budget versus actual results. The CODM also uses net income (loss) in competitive analysis by benchmarking to competitors. The competitive analysis along with the monitoring of budgeted versus actual results are used in assessing performance of the segment and in establishing management's compensation.

Management has determined that Morgan Frank, CEO, is the CODM.

The following table sets forth our condensed consolidated statements of comprehensive income (loss) used by the CODM:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	\$ 10,164	\$ 7,162	\$ 19,506	\$ 12,948
Cost of Revenues	2,206	1,922	4,164	3,506
Gross Margin	7,958	5,240	15,342	9,442
Operating Expenses:				
General and administrative	4,039	1,839	8,506	5,514
Selling and marketing	1,674	1,034	3,205	2,266
Research and development	194	195	402	358
Depreciation and amortization	174	180	366	362
Total Operating Expenses	6,081	3,248	12,479	8,500
Total Other Income (Expense)	(822)	4,569	(7,484)	1,091
Net Income (Loss)	\$ 1,055	\$ 6,561	\$ (4,621)	\$ 2,033

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, 2024 included in our Annual Report on Form 10-K, filed with the SEC on March 20, 2025 (the "2024 Annual Report").

Executive Summary

We continued to realize significant revenue growth during the three months ended June 30, 2025, as compared to the same period in 2024. Revenue for the three months ended June 30, 2025, totaled \$10.2 million, an increase of 42%, as compared to \$7.2 million for the same period of 2024. Revenue for the six months ended June 30, 2025, totaled \$19.5 million, an increase of 51%, as compared to \$12.9 million for the same period of 2024.

Net income for the three months ended June 30, 2025, was \$1.1 million compared to net income of \$6.6 million for the same period in 2024. The decrease in our net income for the three months ended June 30, 2025, was primarily related to the a gain on extinguishment of debt for the three months ended June 30, 2024 that did not recur during the three months ended June 30, 2025 and the change in fair value of derivative liabilities. For the three months ended June 30, 2025, our operating income totaled \$1.9 million, which is flat compared to the same period of 2024.

Net loss for the six months ended June 30, 2025, was \$4.6 million compared to a net income of \$2.0 million for the same period in 2024. The change from net income for the six months ended June 30, 2025 to net loss for the six months ended June 30, 2024, was primarily related to a gain on extinguishment of debt for the six months ended June 30, 2024 that did not recur during the six months ended June 30, 2025 and the change of fair value of derivative liabilities. For the six months ended June 30, 2025, our operating income totaled \$2.9 million, which is an improvement of \$1.9 million compared to the same period of 2024. The increase in operating income was mainly driven by an increase in revenue and gross margin for the six months ended June 30, 2025.

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.") ("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 infrequent charges. EBITDA and Adjusted EBITDA should not be considered as alternatives to net loss 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 infrequent 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 U.S. 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 income (loss).

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net Income (Loss)	\$ 1,055	\$ 6,561	\$ (4,621)	\$ 2,033
Non-GAAP Adjustments:				
Interest expense	1,874	3,783	3,726	7,343
Depreciation and amortization	299	262	573	480
EBITDA	3,228	10,606	(322)	9,856

Non-GAAP Adjustments for Adjusted EBITDA:

Change in fair value of derivative liabilities	(990)	(3,717)	3,911	(1,216)
Other non-cash or infrequent charges:				
Stock-based compensation	1,132	-	2,116	-
Gain on extinguishment of debt	-	(5,310)	-	(5,205)
Severance agreement and legal settlement	-	-	-	585
Release of historical accrued expenses	-	(579)	-	(579)
License and option agreement	-	-	-	(2,500)
Prepaid legal fees expensed from termination of Merger Agreement	\$ -	\$ 457	\$ -	\$ 457
Adjusted EBITDA	\$ 3,370	\$ 1,457	\$ 5,705	\$ 1,398

Results of Operations

(in thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	\$	%	2025	2024	\$	%
Revenue	\$ 10,164	\$ 7,162	\$ 3,002	42%	\$ 19,506	\$ 12,948	\$ 6,558	51%
Cost of revenue	2,206	1,922	284	15%	4,164	3,506	658	19%
Gross margin	7,958	5,240	2,718	52%	15,342	9,442	5,900	62%
Gross margin %	78%	73%			79%	73%		
Operating expenses:								
General and administrative	4,039	1,839	2,200	120%	8,506	5,514	2,992	54%
Selling and marketing	1,674	1,034	640	62%	3,205	2,266	939	41%
Research and development	194	195	(1)	-1%	402	358	44	12%
Depreciation and amortization	174	180	(6)	-3%	366	362	4	1%
Operating income	1,877	1,992	(115)	-6%	2,863	942	1,921	204%
Other income (expense)	(822)	4,569	(5,391)	-118%	(7,484)	1,091	(8,575)	-786%
Net income (loss)	\$ 1,055	\$ 6,561	\$ (5,506)	-84%	\$ (4,621)	\$ 2,033	\$ (6,654)	-327%

Revenue

Revenues for the three months ended June 30, 2025, were \$10.2 million, compared to \$7.2 million for the same period of 2024, an increase of \$3.0 million or 42%. The increase in net sales was primarily driven by the growth in quantity of UltraMIST® disposables and systems sold as well as a strategic focus on price discipline. The quantity of UltraMIST® disposables sold increased by 29% in the three months ended June 30, 2025, as compared to the same period of 2024. The quantity of UltraMIST® systems sold increased by 61% in the three months ended June 30, 2025, as compared to the same period of 2024. Pricing of the UltraMIST® system and disposables also showed growth in the three months ended June 30, 2025, as compared to the same period of 2024; the average selling price of disposables increased 6% in the three months ended June 30, 2025, and the average selling price of systems increased 1% in the three months ended June 30, 2025. Revenue from UltraMIST® totaled 99% of total revenue in the three months ended June 30, 2025, and over 95% in the same period of 2024.

Revenues for the six months ended June 30, 2025, were \$19.5 million, compared to \$12.9 million for the same period of 2024, an increase of \$6.6 million or 51%. The increase in net sales was primarily driven by the growth in quantity of UltraMIST® disposables and systems sold as well as a strategic focus on price discipline. The quantity of UltraMIST® disposables sold increased by 31% in the six months ended June 30, 2025, as compared to the same period of 2024. The quantity of UltraMIST® systems sold increased by 86% in the six months ended June 30, 2025, as compared to the same period of 2024. Pricing of the UltraMIST® system and disposables also showed growth in the six months ended June 30, 2025, as compared to the same period of 2024; the average selling price of disposables increased 7% in the six months ended June 30, 2025, and the average selling price of systems increased 4% in the six months ended June 30, 2025. Revenue from UltraMIST® totaled 99% of total revenue in the six months ended June 30, 2025, and over 94% in the same period of 2024.

Cost of Revenues

Cost of revenues for the three months ended June 30, 2025, was \$2.2 million, compared to \$1.9 million for the same period of 2024. Gross profit as a percentage of revenues was 78% for the three months ended June 30, 2025, compared to 73% for the same period in 2024. This increase in gross margin was largely driven by improved pricing initiatives on our UltraMIST® systems and applicators.

Cost of revenues for the six months ended June 30, 2025, was \$4.2 million, compared to \$3.5 million for the same period of 2024. Gross profit as a percentage of revenues was 79% for the six months ended June 30, 2025, compared to 73% for

the same period in 2024. This increase in gross margin was largely driven by improved pricing initiatives on our UltraMIST® systems and applicators.

General and Administrative

General and administrative expenses for the three months ended June 30, 2025, were \$4.0 million as compared to \$1.8 million for the same period of 2024, an increase of \$2.2 million, or 120%. The increase in the three months ended June 30, 2025, as compared to the same period of 2024, was primarily due to increased headcount expenses of \$1.1 million and non-cash charges for stock-based compensation expense totaling \$0.9 million. There was a release of historical accrued expenses relating to headcount expenses for the three months ended June 30, 2024 of \$0.6 million which did not recur in the three months ended June 30, 2025.

General and administrative expenses for the six months ended June 30, 2025, were \$8.5 million as compared to \$5.5 million for the same period of 2024, an increase of \$3.0 million, or 54%. The increase in the six months ended June 30, 2025, as compared to the same period of 2024, was primarily due to non-cash charges for stock-based compensation expense totaling \$1.7 million and increased headcount expenses of \$1.2 million. There was a release of historical accrued expenses relating to headcount expenses for the six months ended June 30, 2024 of \$0.6 million which did not recur in the three months ended June 30, 2025.

Selling and Marketing

Selling and marketing expenses for the three months ended June 30, 2025, were \$1.7 million as compared to \$1.0 million for the same period of 2024, an increase of \$0.6 million, or 62%. The year-over-year increase in sales and marketing expenses in the three months ended June 30, 2025, was primarily due to increased headcount expenses of \$0.4 million, including commissions as revenues increased, and non-cash charges for stock-based compensation of \$0.2 million.

Selling and marketing expenses for the six months ended June 30, 2025, were \$3.2 million as compared to \$2.3 million for the same period of 2024, an increase of \$0.9 million, or 41%. The year-over-year increase in sales and marketing expenses the six months ended June 30, 2025, was primarily due to increased headcount expenses of \$0.7 million and non-cash charges for stock-based compensation of \$0.4 million; partially offset by decreases in Travel & Entertainment expenses of \$0.1 million and Service Contracts of \$0.1 million.

Research and Development

Research and development expenses for each of the three months ended June 30, 2025, and June 30, 2024, were \$0.2 million. The research and development costs in the three months ended June 30, 2025, remained approximately consistent with the costs in the same period of 2024.

Research and development expenses for each of the six months ended June 30, 2025, and June 30, 2024, were \$0.4 million. The research and development costs in the six months ended June 30, 2025, remained approximately consistent with the costs in the same period of 2024.

Other (Expense) Income, net

Other (expense) income, net consists of the following:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	\$	%	2025	2024	\$	%
Interest expense	\$ (1,874)	\$ (3,783)	\$ 1,909	50%	\$ (3,726)	\$ (7,343)	\$ 3,617	49%
Change in fair value of derivative liabilities	990	3,717	(2,727)	73%	(3,911)	1,216	(5,127)	422%
Gain on extinguishment of debt	-	5,310	(5,310)	-%	-	5,205	(5,205)	-%
Other expense	(27)	(685)	658	96%	(28)	(787)	759	96%
Other income	89	10	79	790%	181	2,800	(2,619)	(94%)
Other (expense) income, net	<u>\$ (822)</u>	<u>\$ 4,569</u>	<u>\$ (5,391)</u>	118%	<u>\$ (7,484)</u>	<u>\$ 1,091</u>	<u>\$ (8,575)</u>	786%

Other (expense) income, net decreased by \$5.4 million to other expense of \$0.8 million for the three months ended June 30, 2025, as compared to other income of \$4.6 million for the same period of 2024. The decrease was primarily driven by a decrease in gain on extinguishment of debt of \$5.3 million and a decrease from the change in the fair value of derivative liabilities of \$2.7 million, partially offset by a decrease in interest expense of \$1.9 million. The change in fair value of derivative liability relates to the valuation of warrants previously issued by the Company.

Other (expense) income, net decreased by \$8.6 million to an expense of \$7.5 million for the six months ended June 30, 2025, as compared to other income of \$1.1 million for the same period of 2024. The decrease was primarily driven by a decrease in gain on extinguishment of debt of \$5.2 million and a decrease from the change in the fair value of derivative liabilities of \$5.1 million, partially offset by a decrease in interest expense of \$3.6 million. The change in fair value of derivative liability relates to the valuation of warrants previously issued by the Company. Other income for the six months ended June 30, 2024 mainly consists of the one-time payment of \$2.5 million related to the Patent and License Agreement as described in Note 16.

Liquidity and Capital Resources

From inception through the year ended December 31, 2023, we incurred losses from operations each year. As of June 30, 2025, we had an accumulated deficit of \$256.0 million. Historically, our operations have primarily been funded from the sale of capital stock, issuances of notes payable, and convertible debt securities.

We have incurred recurring net losses in prior years, currently have a significant accumulated deficit, have negative working capital, and the Senior Secured Note (as defined in Note 8) becomes due in September 2025, which raises substantial doubt about our ability to continue as a going concern for a period of 12 months from the filing of this Form 10-Q.

During the three and six months ended June 30, 2025, and prior fiscal year ended December 31, 2024, we achieved operating income. This is attributable to the implementation and execution of several strategic initiatives, primarily, revenue growth initiatives and a capital raise from a private placement in October 2024, which have positively impacted our operations.

Despite the positive operating income in the current year, we continue to monitor our financial position closely.

In addition to the operational improvements, we are addressing our financial obligations, including the significant portion of debt that matures in September 2025. Management is actively engaged in discussions with lenders and financial institutions to refinance this debt, which could extend the maturity of the debt and provide additional liquidity to support ongoing operations and strategic initiatives.

Although no assurances can be given that our plans to obtain refinancing will be successful or on the terms or timeline we expect, or at all, management believes that the actions taken to date, along with the planned initiatives, will enable the

Company to meet its obligations as they become due and to continue as a going concern.. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms.

The following table presents summarized cash flow information:

(in thousands)	Six Months Ended June 30,	
	2025	2024
Cash flows (used in) provided by operating activities	\$ (524)	\$ 432
Cash flows (used in) investing activities	\$ (1,321)	\$ (206)
Cash flows provided by financing activities	\$ 104	\$ 316

Cash used in operating activities for the six months ended June 30, 2025, totaled \$0.5 million and consisted primarily of a net loss of \$4.6 million and a decrease in net operating assets of \$4.1 million, partially offset by non-cash charges of \$3.9 million related to a change in the fair value of derivative liabilities, \$2.1 million related to stock-based compensation expense, and \$1.1 million related to amortization of debt issuance and debt discounts. Net operating assets consisted primarily of inventory, accrued expenses, prepaid expenses and accounts receivable to support the growth of our operations. In addition, we received \$0.4 million in tenant improvement funds, as described in Note 7 to the financial statement, which partially offsets leasehold improvement investments. The related leasehold improvements are included in purchases of property and equipment under investing activities.

Cash provided by operating activities for the six months ended June 30, 2024 totaled \$0.4 million and consisted primarily of net income of \$2.0 million, partially offset by non-cash charges of \$1.2 million related to a change in the fair value of derivative liabilities and \$3.3 million related to amortization of debt issuance and debt discounts, as well as the receipt of \$2.5 million related to the License and Option Agreement, as further discussed in Note 16 to the financial statements.

Cash used in investing activities for the six months ended June 30, 2025, totaled \$1.3 million and consisted primarily of purchases of property and equipment of \$1.3 million, of which \$0.9 million was related to leasehold improvements at our new headquarters.

Cash used in investing activities for the six months ended June 30, 2024, totaled \$0.2 million and primarily consisted of purchases of property and equipment related to manufacturing equipment.

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 2024 Annual Report on Form 10-K filed with the SEC on March 20, 2025.

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.

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. For further information on the Company's operating segment, refer to Note 18 to the condensed consolidated financial statements.

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 remains elevated, 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 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 June 30, 2025. 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 June 30, 2025.

As of December 31, 2024, the Company identified the following material weaknesses which continue to exist as of June 30, 2025:

The Company lacked internal controls over key accounting and IT processes, including Equity, Financial Reporting, Accounts Payable, Expenses, Revenue, Accounts Receivable, Tax, Cash, Debt, Fixed Assets, Inventory, Commissions, Entity-Level Controls, Human Resources/Payroll, and IT General Controls (change management, operations, and access security). 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. The Company lacked internal resources to analyze and properly apply U.S. GAAP to account for financial instruments included in service agreements with select vendors.

As a result, management concluded that its internal control over financial reporting was not effective as of June 30, 2025.

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.

We plan to remediate and implement these controls for high-risk processes throughout 2025. We 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 deployed 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 June 30, 2025, 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 June 30, 2025, see Note 17 to the condensed consolidated financial statements, which information is incorporated herein by reference.

Item 1A. RISK FACTORS

Except as set forth below, there have been no material changes from our risk factors as previously reported in Part I, Item 1A “Risk Factors” in our 2024 Annual Report.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since our inception. If not utilized, some of our federal and state net operating losses (“NOLs”) carryforwards will begin to expire in various years beginning after 2033. Under the Internal Revenue Code of 1986, as amended, (the “Code”), and certain similar state tax provisions, we are generally allowed to carry forward our NOLs from a prior taxable year to offset our future taxable income, if any, until such NOLs are used or expire, subject to certain limitations. The same is true of other unused tax attributes, such as tax credits. In addition, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. During the quarter ended June 30, 2025, we completed an IRC Section 382 analysis of our tax attributes. That analysis showed that \$44.2 million of our NOL tax attributes would expire before becoming available under our limitation as a result of shifts in our ownership. We have adjusted our tax attributes to account for this limitation.

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 June 30, 2025, 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

<u>Exhibit No.</u>	<u>Description</u>
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 as of 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 10.1 to the Form 8-K filed with the SEC on April 26, 2024).
2.4	Amended 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 June 3, 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	Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on March 7, 2025).
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 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).
3.10	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).
3.11	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).
3.12	Certificate of Amendment of the Articles of Incorporation, effective as of October 18, 2024 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on October 18, 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: August 7, 2025

By: */s/ Morgan Frank*

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

Dated: August 7, 2025

By: */s/ Peter Sorensen*

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