UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2025

or

☐ **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 Charter)

Nevada	**20-1176000**
(State or Other Jurisdiction of Incorporation)	**(I.R.S. Employer Identification No.)**
9600 W. 76th St, Ste 118 **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

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

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 file). 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrants' executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☒

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation only, that the registrant's directors, executive officers and greater than 10% stockholders are affiliates of the registrant), based upon the closing sale price of the registrant's common stock on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was $233.3 million.

As of March 24, 2026, there were issued and outstanding 8,594,209 shares of the registrant's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive proxy statement relating to our 2026 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

SANUWAVE Health, Inc.
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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K of SANUWAVE Health, Inc. and its subsidiaries ("Sanuwave" or the "Company") contains forward-looking statements. All statements in this Annual Report on Form 10-K, 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, but are not limited to, statements regarding: results of operations, liquidity, and operations, restrictions and new regulations on our operations and processes, including the execution of clinical trials; the Company's future financial results, operating results, and projected costs; market acceptance of and demand for UltraMIST®; the estimated size of the wound care market; 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 United States ("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 this report, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Other risks and uncertainties are and will be disclosed in the Company's subsequent filings with the U.S. Securities and Exchange Commission (the "SEC").

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. Except to the extent required by law, the Company does not undertake, and expressly disclaims, any duty, or obligation to revise or update any forward-looking statements whether as a result of new information, future events, changes in assumptions or otherwise.

Except as otherwise indicated by the context, references in this Annual Report on Form 10-K to "we," "us," and "our" are to the consolidated business of the Company.

EXPLANATORY NOTE REGARDING RESTATEMENT

This Annual Report on Form 10-K for the year ended December 31, 2025, includes the restatement of previously issued consolidated financial statements, data, and related disclosures for the following periods:

- The audited consolidated financial statements and related disclosures as of and for the year ended December 31, 2024, as included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 (see Part II, Item 8);
- Unaudited quarterly financial information as of and for the three months ended March 31, 2024, the three and six months ended June 30, 2024, and the three and nine months ended September 30, 2024 (see Part II, Item 8);
- Unaudited quarterly financial information as of and for the three months ended March 31, 2025, the three and six months ended June 30, 2025, and the three and nine months ended September 30, 2025 (see Part II, Item 8).

During the preparation of this Annual Report on Form 10-K, the Company determined that it had not appropriately accounted for certain transactions under US GAAP. For the years ended December 31, 2024 and 2025, presented, the transactions related to sales tax, which led to an understatement of accrued expenses and a corresponding, non-recurring increase in expense due to the recognition of previously unrecorded taxes, associated interest, and penalties. For the

quarters ended March 31, June 30, and September 30, 2025, the Company also determined that revenue was overstated and current portion of contract liabilities and contract liabilities, less current portion were understated related to extended warranties.

In accordance with Staff Accounting Bulletin ("SAB") 99, *Materiality*, and SAB 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, the Company evaluated the materiality of the errors from qualitative and quantitative perspectives, individually and in the aggregate, and concluded that the errors in aggregate were material to the consolidated financial statements for the affected periods.

Accordingly, previously issued financial information for the periods indicated above, as included in the Company's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, earnings releases, and similar communications, should no longer be relied upon and is superseded by the information contained in this Annual Report.

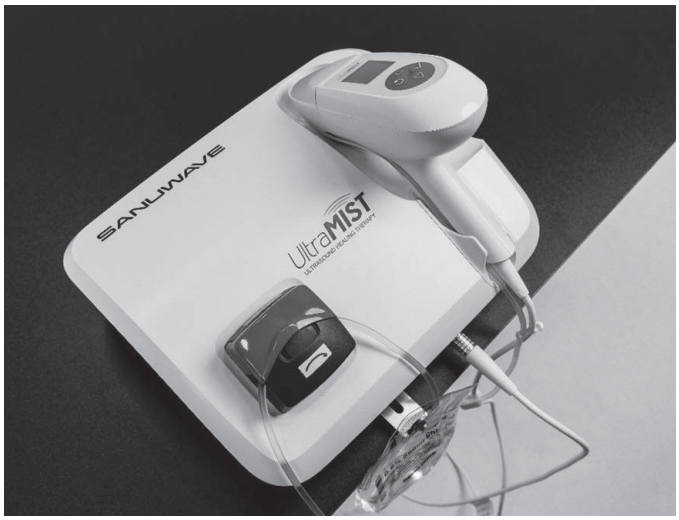
Item 1. BUSINESS

Overview

Sanuwave is a medical device company providing directed energy products into the wound care space. Our mission is to improve patient lives and outcomes by developing and marketing effective, easy to use products to decrease wound burden, lessen healing times, and reduce patient pain.

Our focus is regenerative medicine utilizing noninvasive ultrasound to produce a biological response promoting the repair and regeneration of tissue, musculoskeletal, and vascular structures. The Company's patented and FDA cleared product is the UltraMIST® system, which is used to treat a variety of acute and chronic wounds. The Company is backed by an intellectual property ("IP") portfolio of over 60 patents.

In the year ended December 31, 2025, we had total revenues of $44.1 million, a 35% increase from revenues of $32.6 million in the year ended December 31, 2024. UltraMIST systems and consumables represented approximately 99% of 2025 revenues versus 98% of revenues in 2024.



Our Products and Services:

The Company develops and markets directed energy products that utilize ultrasound technology. UltraMIST is the only commercial product currently marketed by the Company.

UltraMIST

The UltraMIST system delivers low frequency, non-thermal ultrasound to target tissues using a fluid mist to transmit energy in a non-contact, pain free fashion. This energy penetrates deep into wound beds to promote healing while reducing inflammation, killing bacteria and biofilms, and increasing the growth of blood vessels in the wound and peri-wound.

This proprietary technology has been shown to speed healing and reduce reported pain. UltraMIST has been cleared by the FDA for wound healing and debridement for a variety of acute and chronic wounds including:

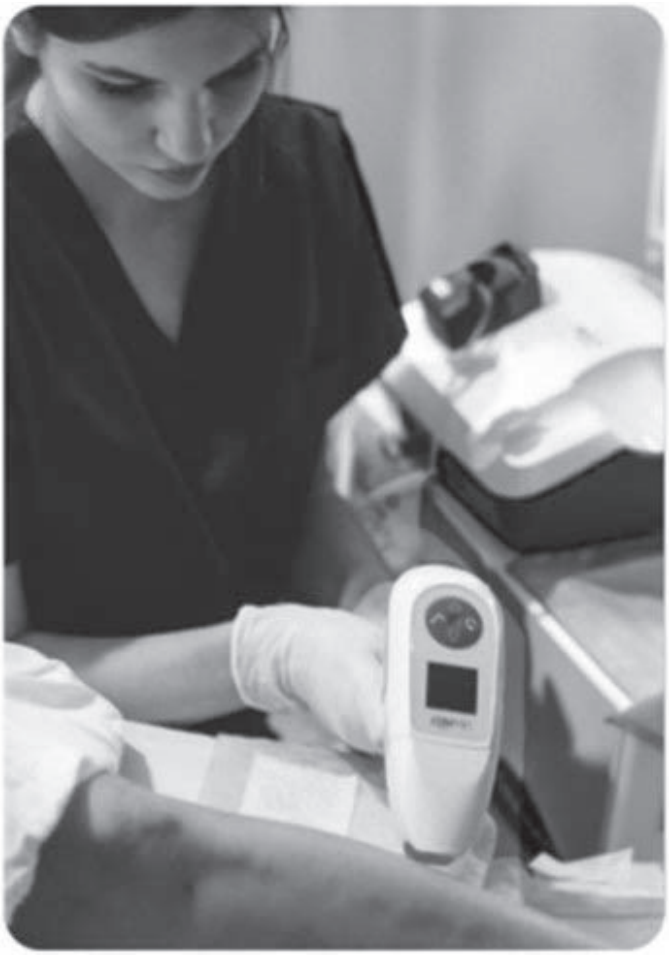
- diabetic foot ulcers,
- venous leg ulcers,
- split thickness wounds/skin grafts,
- deep tissue pressure injuries,
- surgical wounds, and
- many more wound types.

The UltraMIST system is cleared for marketing in the U.S. by the FDA (K140782) and has the Centers for Medicare and Medicaid Services ("CMS") category one reimbursement under code 97610. The UltraMIST system treatment must be administered by a healthcare professional.

The UltraMIST system is highly portable and is used in hospitals, physician's offices, wound centers, nursing homes, skilled nursing facilities, and by mobile wound care providers serving patient homes. Treatment may be provided by a doctor, nurse, nurse practitioner, or physical therapist.

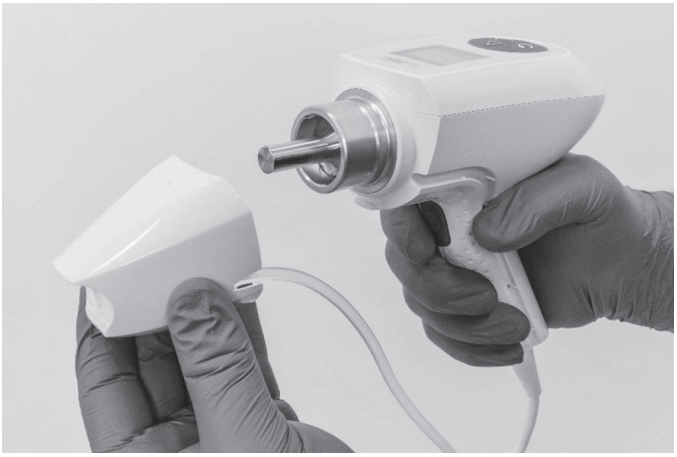
Treating chronic wounds is a difficult and time-consuming process. Current modalities for wound management typically involve the use of ointments and liquid solutions, specialized bandages, topical skin substitutes, negative pressure, or hyperbaric oxygen. Despite this, many patients are left with chronic wounds resistant to healing.

Sanuwave's UltraMIST protocol is at the forefront of improving the standard of care for advanced and chronic wounds. Our solutions help expedite the healing process at a cellular level, a better and simpler alternative that can lead to improved patient outcomes and enhanced quality of life.



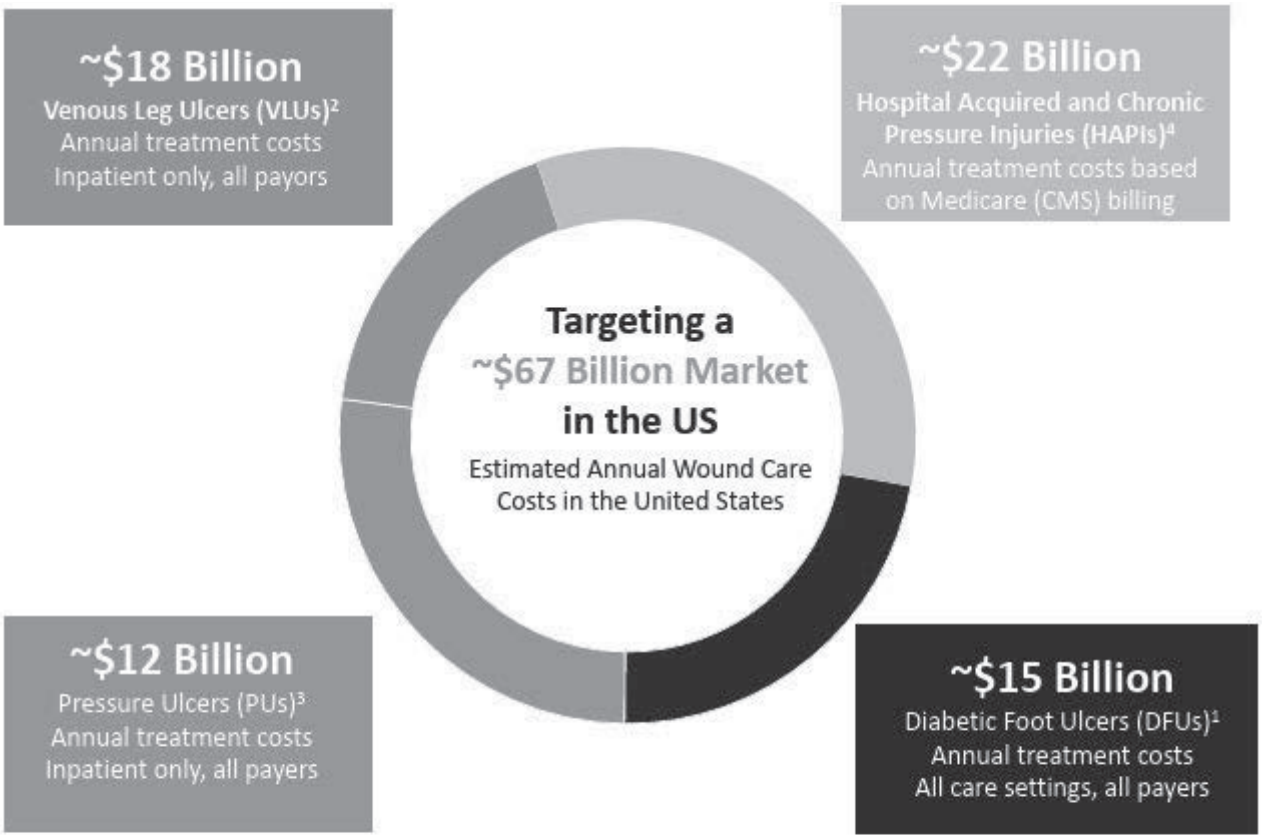
As the UltraMIST device never touches the wound, the treatment is painless and patients report a significant reduction in pain post treatment. Significant clinical research demonstrates reductions in healing time, patient pain, and other indicators of patient healing (more clinical information can be found on our website: https://sanuwave.com/clinical). The UltraMIST system is in use with many top hospitals and wound care providers across the United States. Typical treatment time is six minutes (and ranges from three to 20 minutes).

UltraMIST is sold using a simple “razor/razor blade” model. Customers purchase an UltraMIST system and then each treatment utilizes a sterile, single use applicator sold in cases of 12. UltraMIST consumables revenues constitute the majority of Sanuwave revenue amounting to approximately 58% of total revenues in 2025 and are expected to remain the largest revenue stream for the Company. As of December 31, 2025, there were 1,292 active systems in the field. Active systems are defined as those owned by customers who have ordered consumable applicators within the last 6 months (or within their expected ordering timeframe for those who order infrequently). In the event that customers are known to have discontinued use, their systems may be removed from this total earlier.



Market

We estimate the wound care market exceeds $67 billion per year in the United States and is spread among a number of key categories



1) Rice et al. Diabetes Care 2014;37:651-658.
2) Rice et al. J Med Econ. 2014;17-(5): 347-356.
3) National Pressure Ulcer Advisory Panel (NPUAP).
4) Nussbaum, Carter, Fife Value Health 2018.

With an aging population and high incidence of obesity, diabetes, cancers, and autoimmune disorders, the Company believes this market is likely to continue to expand.

Strategy

The Company is focused on building a direct sales force and distribution network to market the UltraMIST product in the United States and to assess potential expansion abroad. The Company sees two broad trends favoring UltraMIST adoption:

transition to evidence-based medicine in wound care and “care to the edge”, as care is being directed away from hospital settings in an effort to treat patients where they are to increase ease of care and to reduce risks of nosocomial infection.

Reimbursement is being restructured around efficacy and cost effectiveness as payors, physicians, and patients seek better outcomes for less money.

The Company believes that both trends are favorable to Sanuwave.

We aim to change the wound care space by bringing cost effective, easy to use technology to market, and putting it into the hands of providers who can easily adopt it as well as integrate it into their workflow and patient treatment plans. To generate broad adoption, a technology needs to be more than just effective, it needs to be both user and patient friendly. Our goal is to provide the technology that physicians need to provide the wound care that patients want.

Traditionally, many patients have been resistant to seek wound care because treatments are long in duration, difficult, involve cumbersome medical devices that must be worn long term, and are frequently painful. The Company seeks to overcome such patient and provider objections in order to expand access to high quality, modern wound care and to get more patients seen and seen earlier. By lowering the bar of “willing to seek treatment,” Sanuwave seeks to engage with patients and wounds before they become severe.

By providing an effective, pain free system with short treatment times that practitioners can learn to use via video conference and for which nationwide category 1 CMS reimbursement is already available, the Company seeks to appeal to the “three P’s.”

- Patients want to get better sooner and to experience less pain.
- Physicians want patients to get better but also need to be able to integrate care into their practice flow and economic models.
- Payors want to see patients get better faster and to receive early treatment often outside of hospital settings as such treatments save money.

When the needs of Patients, Physicians, and Payors are aligned, markets are ready adopters of products and markets are ready for change.

The Company seeks to move wound care from a more “transactional” mindset to a consultative one, helping practitioners work effective wound treatment into the practice flows and patients' lives. No one wants to live with chronic wounds. We do not believe they should have to.

Sales, Marketing and Distribution

The Company sells systems through a combination of direct sales representatives, independent distributors, and resellers. The systems are used in hospitals, clinics, and alternate care facilities. Our primary sales are in the United States.

Manufacturing

The Company has developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantities of our products.

The Company sources the generator and treatment wand components of its products from Nortech Systems, Inc in Maple Grove, MN. Our generators and treatment wands are manufactured in accordance with applicable quality standards and applicable industry and regulatory standards. In addition, the Company performs the final product testing for generators and treatment wands internally.

The Company is party to a manufacturing supply agreement with Dynamic Group in Ramsey, MN, covering the applicator component of our products. Our applicators are manufactured in accordance with applicable quality standards and applicable industry and regulatory standards. Dynamic Group produces the applicators and applicator kits for our products.

Our facility in Eden Prairie, MN consists of 20,019 square feet and provides office, product development, quality control, and warehouse space. It is an FDA-registered facility and is International Organization for Standardization (ISO) 13485:2016 certified.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, technology, and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing upon our proprietary rights. The Company seeks to protect our proprietary position by, among other methods, filing United States and selected foreign patent applications and United States and selected foreign trademark applications related to our proprietary technology, inventions, products, and improvements that are important to the development of our business. Effective trademark, service mark, copyright, patent, and trade secret protection may not be available in every country in which our products are made available. The protection of our intellectual property may require the expenditure of significant financial and managerial resources.

Patents

The Company considers the protection afforded by patents important to our business. The Company intends to seek and maintain patent protection in the United States and select foreign countries, where deemed appropriate for products that the Company develops. As of December 31, 2025, Sanuwave held more than 60 issued or pending patents worldwide that cover various aspects of the Company's technology. In general, our patents are effective, ranging from 6 months to 15 years. There are no assurances that any patents will result from our patent applications, or that any patents that may be issued will protect our intellectual property, or that any issued patents or pending applications will not be successfully challenged, including as to ownership and/or validity, by third parties. In addition, if the Company does not avoid infringement of the intellectual property rights of others, the Company may have to seek a license to sell our products, defend an infringement action or challenge the validity of intellectual property in court. Any current or future challenges to our patent rights, or challenges by us to the patent rights of others, could be expensive and time consuming.

The Company believes that our owned and licensed patent rights provide a competitive advantage with respect to others that might seek to utilize certain of our apparatuses and methods incorporating low frequency and non-contact ultrasound and extracorporeal acoustic pressure shockwave technologies that the Company has patented. However, the Company does not hold patent rights that cover all of our products, product components, or methods that utilize our products. The Company also has not conducted a competitive analysis or valuation with respect to our issued and pending patent portfolio in relation to our current products and/or competitor products.

In August 2020, we entered into an asset purchase agreement with Celularity Inc. ("Celularity"), pursuant to which we acquired all of Celularity's assets related to the MIST Therapy System and UltraMIST System, including all intellectual property and trademarks related to MIST and UltraMIST. These assets are for use in low frequency and non-contact ultrasound to treat wounds.

Trademarks

Since other products on the market compete with our products, the Company believes that our product brand names are an important factor in establishing and maintaining brand recognition.

The Company has the following trademark registrations: SANUWAVE® (United States, European Community, Canada, Japan, Switzerland, United Kingdom, Taiwan and under the Madrid Protocol), Energy First® (United States), Healing Today, Curing Tomorrow® (United States), and UltraMIST® (United States).

Through the acquisition of UltraMIST®/MIST assets from Celularity Inc., the Company is the owner of the Celleration® (United States, Australia, Europe Community, and Japan), Proven Healing® (Madrid Protocol, European Community, and United Kingdom), MIST Ultrasound Healing Therapy & Design® (United States), MIST® (United States), MIST Therapy® (United States), and MIST & Design® (United States) registered trademarks.

The Company also maintains other trademark registrations.

Competition

The advanced wound care market is highly competitive and includes a broad range of technologies used to promote wound healing, manage exudate, control infection, and support tissue regeneration. The Company competes with manufacturers of advanced wound dressings, negative pressure wound therapy systems, cellular and tissue-based products, biologic grafts, and energy-based wound treatment technologies. Many of these companies have significantly greater financial, marketing, sales, and research resources than the Company.

Major participants in the wound care market include multinational medical device and wound care companies such as Solventum, Smith & Nephew, Molnlycke Health Care, Essity, Coloplast, and Convatec, which offer portfolios of advanced wound dressings, wound management products, and negative pressure wound therapy systems.

The Company also competes with manufacturers of cellular and tissue-based products and biologic wound therapies, including Organogenesis, MiMedx Group, Integra LifeSciences, Vericel, and Kerecis.

In addition, the Company competes with energy-based wound treatment technologies, including ultrasound systems developed by Arobella Medical and NanoVibronix, and acoustic wave technologies developed by SoftWave Tissue Regeneration Technologies. Wound imaging and diagnostic technologies from companies such as MolecuLight and MIMOSA Diagnostics may also influence treatment decisions in wound care.

The UltraMIST therapy system, delivers non-contact low-frequency ultrasound therapy intended to promote wound healing through mechanical stimulation of tissue. The Company believes UltraMIST may offer advantages in certain settings due to its non-contact application, ease of use, and patient tolerability. Healthcare providers, however, may choose among many treatment alternatives depending on clinical protocols, reimbursement considerations, and physician or facility preference.

The Company's products also compete with conventional wound care approaches, including surgical or sharp debridement, standard wound dressings, compression therapy, and other established wound management practices. Competitive factors include clinical outcomes, ease of use, patient comfort, reimbursement coverage, cost, and the availability of supporting clinical evidence.

Regulatory Matters

Food and Drug Administration (FDA) Regulation

Each of our products must be approved or cleared by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products.

In the United States, the FDA subjects medical products to rigorous review. If the Company does not comply with applicable requirements, the Company may be fined, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products, and the Company may be criminally prosecuted. Failure to comply with the law could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension or withdrawal of product approval, injunctions, or criminal prosecution.

The FDA has determined that our technology and products constitute "medical devices." The FDA determines what center or centers within the FDA will review the product and its indication for use and determines under what legal authority the product will be reviewed. For the current indications, our products are being reviewed by the Center for Devices and Radiological Health. However, the Company cannot be sure that the FDA will not select a different center and/or legal authority for one or more of our other product candidates, in which case the governmental review requirements could vary in some respects.

FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy:

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: special controls, pre-market notification (510(k)), specific controls such as performance standards, patient registries, and post market surveillance, and additional controls such as labeling and adherence to quality system regulations; and
- Class III: special controls and approval of a pre-market approval (PMA) application.

Each of our products require FDA authorization prior to marketing, by means of either a 510(k) clearance or a PMA approval. To request marketing authorization by means of a 510(k) clearance, the Company must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device, has the same intended use, and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than does a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then a company must submit, and the FDA must approve, a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing, and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with quality system regulation requirements, which govern testing, control, documentation, and other aspects of quality assurance with respect to manufacturing. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling, or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Obtaining medical device clearance, approval, or licensing in the United States or abroad can be an expensive process. International fee structures vary from minimal to substantial, depending on the country. In addition, the Company is subject to annual establishment registration fees in the United States and abroad. Device licenses require periodic renewal with associated fees as well. Currently, the Company is registered as a Small Business Manufacturer with the FDA and as such is subject to reduced fees. If, in the future, our revenues exceed a certain annual threshold limit, the Company may not qualify for the Small Business Manufacturer reduced fee amounts and will be required to pay full fee amounts.

Post-Approval Regulation of Medical Devices

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- the FDA quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experiences associated with use of the product; and
- post market surveillance, including documentation of clinical experience and follow-on, confirmatory studies.

The Company continues to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories.

International sales of medical devices manufactured in the United States that are not approved or cleared by the FDA are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Exported devices may also fall under the jurisdiction of the United States Department of Commerce/ Bureau of Industry and Security and compliance with export regulations may be required for certain countries.

Manufacturing Certifications

The Medical Device Single Audit Program ("MDSAP")

MDSAP allows a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory authorities (RAs). Five RAs including: The Australian Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, MHLW/PMDA (Japan), and the FDA participated in a three-year MDSAP Pilot which concluded in December 2016. These RAs have continued to participate in MDSAP since the program moved into its operational phase starting January 2017, with Health Canada making a full transition from the Canadian Medical Devices Conformity Assessment System (CMDCAS) to MDSAP in January of 2019.

MDSAP uses recognized third-party auditors – auditing organizations (AOs) – to conduct a single quality management system audit that satisfies the requirements of multiple regulatory authorities. Manufacturers only needed to comply with the regulations from the jurisdictions where they sell their products. The MDSAP certificate indicates that a manufacturer complies with the regulatory requirements for the markets defined in the certificate. The certificate does not represent marketing authorization, nor does it require any regulatory authority to issue a marketing authorization or endorsement to the device manufacturer.

The Company has been certified to the MDSAP requirements for the U.S., most recently successfully completing a MDSAP recertification audit in June 2025. Audit to additional countries will be conducted if expansion to those markets is considered. This certificate is valid for three years. Annual surveillance audits are required to maintain this certification. A surveillance will be conducted in 2026.

Manufacturing cGMP Requirements

Manufacturers of medical devices are required to comply with FDA manufacturing requirements contained in the FDA's current Good Manufacturing Practices ("cGMP") set forth in the quality system regulations promulgated under section 520 of the Federal Food, Drug and Cosmetic Act. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-PMA approval inspection before the Company can use it. The Company and some of our third-party service providers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the

imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

United States Anti-Kickback and False Claims Laws

In the United States, there are Federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in Federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians, and other potential purchasers of such products. Other provisions of Federal and state laws provide civil and criminal penalties for presenting, or causing to be presented, to third-party payors for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, certain states have implemented regulations requiring medical device and pharmaceutical companies to report all gifts and payments over $50 to medical practitioners. Although we intend to structure our future business relationships with clinical investigators and purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by Federal or state enforcement officials under these laws.

Third Party Reimbursement

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payors. Third party payors include governmental programs such as Medicare and Medicaid, private insurance plans, and workers' compensation plans. Even though a new product may have been approved or cleared by the FDA for commercial distribution, we may find limited demand for the device until adequate history of reimbursement has been obtained from governmental and private third-party payors.

The CPT code for UltraMIST is 97610. This Category 1 code describes a system used in wound care that uses low frequency ultrasonic energy to atomize a liquid and deliver continuous low frequency ultrasound to the wound bed.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

We believe that the overall escalating costs of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. In addition, recent healthcare reform measures, as well as legislative and regulatory initiatives at the Federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payor coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

Confidentiality and Security of Personal Health Information and Sensitive Personal Information

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations (collectively referred to as "HIPAA"), contains provisions that protect individually identifiable health information from unauthorized use or disclosure by covered entities and their business associates. The Office for Civil Rights of the U.S. Department of Health and Human Services

("HHS"), the agency responsible for enforcing HIPAA, has published regulations to address the privacy (the "Privacy Rule") and security (the "Security Rule") of protected health information ("PHI"). HIPAA also requires that all providers who transmit claims for health care goods or services electronically utilize standard transaction and data sets and to standardize national provider identification codes. In addition, the American Recovery and Reinvestment Act enacted the HITECH Act, which extends the scope of HIPAA to permit enforcement against business associates for a violation, establishes new requirements to notify the Office for Civil Rights of HHS of a breach of HIPAA, and allows the Attorneys General of the states to bring actions to enforce violations of HIPAA.

We anticipate that, as we expand our business, we may in the future be a covered entity under HIPAA. We have adopted policies and procedures to comply with the Privacy Rule, the Security Rule and the HIPAA statute as such regulations become applicable to our business.

In addition to HIPAA, many states have laws that govern the processing, collection, use, disclosure, transfer, storage, disposal and protection of health-related and other sensitive and personal information. These state law protections are different and, in some cases, may be more stringent, broader in scope, or offer greater individual rights with respect to sensitive health information than HIPAA. These laws are evolving rapidly and may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, ("CCPA") gives California residents individual privacy rights to access and delete their personal information, opt out of certain personal information sharing, limit the use of their sensitive personal information, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. The CCPA also established a new California agency, the California Privacy Protection Agency, which is authorized to issue new substantive regulations and has independent enforcement power alongside the California Attorney General. These additional rights and the establishment of an agency with independent enforcement powers are expected to increase data breach litigation and government enforcement activity in California. Comprehensive privacy legislation similar to the CCPA has been adopted in many other U.S. states. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In addition to the state comprehensive data privacy laws, recent years have brought substantial changes to the federal and state treatment of non-HIPAA consumer health information. At the federal level, the FTC brought three enforcement actions in 2023 against a range of companies that handle electronic health information relating to collection and disclosure of non-HIPAA covered consume health information under Section 5 of the FTC Act, two of which included allegations made under the FTC's Health Breach Notification Rule ("HBNR"). The FTC's focus on health information continued in 2024 with changes to the HBNR that clarified its scope and emphasized applicability to non-HIPAA health care providers as well as three additional enforcement actions against companies for their use of health information for advertising purposes. On the state level, Washington and Nevada have adopted significant new legislation addressing businesses treatment of consumer health information and Connecticut added more stringent protections for health information to its existing comprehensive state privacy law. In both Washington and Nevada's laws, there are restrictive provisions limiting collection and disclosure of consumer health information, and Washington's law provides a separate private right of action for violations.

We intend to adopt policies and procedures to ensure material compliance with state laws regarding the confidentiality of health information as such laws become applicable to us and to monitor and comply with new or changing state laws on an ongoing basis.

Environmental and Occupational Safety and Health Regulations

Our operations are subject to extensive Federal, state, provincial and municipal environmental statutes, regulations and policies, including those promulgated by the Occupational Safety and Health Administration, the United States Environmental Protection Agency, Environment and Climate Change Canada, Alberta Environment and Protected Areas, the Department of Health Services, and the Air Quality Management District, that govern activities and operations that may have adverse environmental effects such as discharges into air and water, as well as handling and disposal practices for solid and hazardous wastes. Some of these statutes and regulations impose strict liability for the costs of cleaning up, and for damages resulting from, sites of spills, disposals, or other releases of contaminants, hazardous substances and other

materials and for the investigation and remediation of environmental contamination at properties leased or operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. In addition, we may be subject to claims and lawsuits brought by private parties seeking damages and other remedies with respect to similar matters. We have not to date needed to make material expenditures to comply with current environmental statutes, regulations and policies. However, we cannot predict the impact and costs those possible future statutes, regulations and policies will have on our business.

Employees

As of December 31, 2025, we had a total of 55 full time employees in the United States. Of these, 15 were engaged in research and development which also includes clinical, regulatory, and quality. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

Corporate Information

We were formed as a Nevada corporation in 2004. Our corporate headquarters address is 9600 W. 76th Street, Suite 118, Eden Prairie, MN, 55344, and our main telephone number is (800) 545-8810 or (952) 656-1029.

Available Information

We maintain a website at www.sanuwave.com. We make available on our website, free of charge, our periodic reports and registration statements filed with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. Our internet site and the information contained on or connected to that site are not incorporated by reference into this Annual Report on Form 10-K. The SEC also maintains a website at www.sec.gov that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this Annual Report on Form 10-K, including the consolidated financial statements and the related notes, before purchasing our common stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In any such event, the market price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to our Business

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting or disclosure controls and procedures, it may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations, which may adversely affect our business, financial condition, and results of operations.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We are taking certain measures to remediate these material weaknesses as discussed further in Part II, Item 9A of this Annual Report on Form 10-K; however, such material weaknesses had not been remediated as of December 31, 2025. In addition, due to the material weaknesses in internal control over financial reporting, we have also determined that our disclosure controls and procedures were not operating effectively as of December 31, 2025. The material weaknesses will not be considered remediated until management completes the design and implementation of the applicable controls, such controls have operated effectively for a sufficient period of time, and management has concluded, through testing, that these controls are operating effectively.

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2025, we engaged a third party to conduct a sales and use tax nexus study. Management used this third party report and identified that we had a historical state and local sales tax liability related to prior periods. We are required and subject to collect and remit sales and use tax in state and local jurisdictions where we have economic and physical nexus. During the year ended December 31, 2025, we determined that a sales tax liability, related to the periods of 2022 through 2025, was probable and determined an estimated liability for sales transactions processed in jurisdictions where we had not previously reported. Management has concluded that the error was material to the previously issued annual financial statements and, accordingly, a restatement of prior period financial information was required in accordance with U.S. GAAP and SEC rules. For further information, refer to Note 2 to the consolidated financial statements.

There can be no assurance as to when the material weaknesses will be remediated. These remediation measures will be time consuming, will result in us incurring significant costs, and will place significant demands on our financial and operational resources.

We cannot assure that the measures we have taken to date and may take in the future will be sufficient to remediate the control deficiencies that led to our material weaknesses in internal control over financial reporting or that they will prevent potential future material weaknesses. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the possibility of human error, and the risk of fraud. Any failure to design, implement, and maintain effective internal control over financial reporting and effective disclosure controls and procedures, or any difficulties encountered in their implementation or improvement, could 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, financial condition, results of operations, and stock price.

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 loss ("NOL") 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.

Our history of operating losses and prior reliance on external financing has raised, and could again raise, substantial doubt about our ability to continue as a going concern.

The Company has historically experienced recurring net losses, accumulated deficits, negative working capital, and significant debt maturities, which raised substantial doubt about its ability to continue as a going concern.

During the year ended December 31, 2025, management executed a comprehensive refinancing of the Company's secured debt with a new lender, which extended the maturity of the Company's principal debt obligations and established a secured revolving credit facility. In addition, the Company generated net income of $11.8 million for the year ended December 31, 2025, and achieved positive operating income for both the years ended December 31, 2025, and December 31, 2024.

Management evaluated the Company's financial condition and projected cash flows for the twelve months following the issuance of the consolidated financial statements included in this Annual Report on Form 10-K. Based on the debt refinancing, improved operating performance, and expected cash inflows from operations, we believe that our anticipated cash flows from operations, and cash on hand will be sufficient to satisfy our working capital needs, capital expenditures and debt repayments for at least twelve months from the issuance date of these consolidated financial statements.

However, there can be no assurance that the Company will continue to generate positive operating results or maintain sufficient liquidity in the future. Management will continue to monitor the Company's financial position, operating results, and compliance with debt covenants. If the Company is unable to sustain improved operating performance, maintain access

to financing, or comply with applicable debt covenants, its financial condition and ability to continue operations could be materially adversely affected.

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

Prior to 2025, we experienced negative operating cash flows and funded our operations primarily from proceeds received from sales of our capital stock, the issuance of promissory notes and convertible promissory notes, the issuance of notes payable to related parties, and product sales. We may seek to obtain additional funds in the future either through equity or debt financings or through strategic alliances with third parties, either alone or in combination with equity financings. These financings could result in substantial dilution to the holders of our common stock or require contractual or other restrictions on our operations or on alternative business opportunities that may be available to us. If we can raise additional funds by issuing debt securities, these debt securities could impose significant additional restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material adverse effect on our business, financial condition, and results of operations, or threaten our ability to continue as a going concern.

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

- unanticipated expenditures in research and development or manufacturing activities;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our products;
- unforeseen changes in healthcare reimbursement for procedures using any of our approved products;
- inability to train a sufficient number of physicians to create a demand for any of our approved products;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- unforeseen problems with our third-party manufacturers, service providers or specialty suppliers of certain raw materials;
- unanticipated difficulties in operating in international markets;
- unanticipated financial resources needed to respond to technological changes and increased competition;
- unforeseen problems in attracting and retaining qualified personnel;
- the impact of changes in U.S. health care law and policy on our operations;
- enactment of new legislation or administrative regulations;
- the application to our business of new court decisions and regulatory interpretations;
- claims that might be brought in excess of our insurance coverage;
- delays in timing of receipt of required regulatory approvals;
- the failure to comply with regulatory guidelines; and
- the uncertainty in industry demand and patient wellness behavior.

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

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

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

expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made.

Changes in reimbursement affecting the wound care market could adversely affect our customers and indirectly reduce demand for our products.

The wound care market is highly dependent on reimbursement from governmental and private third-party payors, including CMS and Medicare Administrative Contractors. CMS and other payors periodically revise coverage policies, payment levels, coding guidance, and utilization rules for wound care products and procedures, including cellular and tissue-based products for skin wounds ("skin substitutes" or allografts) and other advanced wound care therapies.

Although our UltraMIST system is not a skin substitute or allograft product, many of our customers operate within care settings where these products are frequently used as part of broader wound care treatment protocols. Significant reimbursement reductions or policy changes affecting such products or procedures could negatively affect the economics of wound care practices, hospitals, and other providers. These changes could reduce provider revenues, alter treatment protocols, or limit capital expenditures, which could indirectly reduce demand for our products.

Reimbursement policies are determined by governmental and private payers and are outside our control. Changes affecting the wound care reimbursement environment could adversely affect the financial condition of our customers and have a material adverse effect on our business, financial condition, and results of operations.

Many of our product component materials are only produced by a single supplier for such product component. If we are unable to obtain product component materials and other products from our suppliers that we depend on for our operations, or find suitable replacement suppliers, our ability to deliver our products to market will likely be impeded, which could have a material adverse effect on us.

We depend on suppliers for product component materials and other components that are subject to stringent regulatory requirements. Many of our product component materials are only produced by a single supplier for such product components. While we believe that alternative manufacturers and suppliers offering similar components are available on an as-needed basis and could be engaged in a reasonable period of time, there can be no assurance that the loss of these suppliers will not result in a disruption to our production. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. Certain of our suppliers must be approved by regulatory authorities, which could delay our efforts to establish additional or replacement suppliers for these materials.

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

The loss of our key management would likely hinder our ability to execute our business plan.

As a small company with fewer than 60 employees, our success depends on the continuing contributions of our management team and qualified personnel. Turnover, transitions or other disruptions in our management team and personnel could make it more difficult to successfully operate our business and achieve our business goals and could adversely affect our results of operation and financial condition. Our success depends in large part on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical, biotechnology and medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

We face an inherent risk of liability if the use or misuse of our products results in personal injury or death.

The sale of products may expose us to product liability claims which could result in financial loss. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts or scope, to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management team and other resources, and adversely impact or eliminate the prospects for commercialization of

the product candidate, or sale of the product, that is the subject of any such claim. Although we do not promote any off-label use, off-label uses of products are common, and the FDA does not regulate a physician's choice of treatment. Off-label uses of any of our products may subject us to additional liability.

We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.

We rely to a large extent upon sophisticated information technology systems to operate our businesses, some of which are managed, hosted, provided and/or used by third parties or their vendors. We collect, store, and transmit large amounts of confidential information, and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact our operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media, or storage devices. We could also experience, and in some cases have experienced in the past, a business interruption, theft of confidential information, financial theft, or reputational damage from industrial espionage attacks, malware, spoofing or other cyber-attacks, which may compromise our system infrastructure, lead to data leakage, either internally or at our third-party providers, or materially adversely impact our financial condition.

We have previously disclosed that we have experienced cybersecurity breaches from email spoofing. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business, and reputational harm to us.

If we are unable to expand, manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenue.

Building the requisite sales, marketing and distribution capabilities to successfully market and sell our products continues to be expensive and time-consuming and requires significant attention from our leadership team to manage. Any failure or delay in the expansion of our sales, marketing or distribution capabilities would adversely impact the commercialization of our products. Additionally, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties on the commercialization of our products. If we are unable to enter into arrangements with such third parties on acceptable terms or at all, we may not be able to successfully commercialize our products.

If we fail to properly manage our growth effectively, our business could suffer.

We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources including but not limited to procuring sufficient office, warehouse, and production space to successfully operate our business and the inherent difficulties arising from acquiring, managing, or moving between such operating spaces. In particular, the hiring of our direct sales force requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must continue to successfully increase manufacturing output to meet expected customer demand. We may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, such as skilled operators who can assemble our product, among other problems. Any of these problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenue.

Future growth will continue to impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure.

In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and may have an adverse effect on our business, financial condition, and results of operations.

We generate a portion of our revenue internationally and are subject to various risks relating to our international activities, which could adversely affect our operating results.

On an annual basis, less than one percent of our revenue comes from international sources. While we have no current plan to materially expand our international operations, there can be no assurance we will not pursue such an expansion in the future. Engaging in international business involves several difficulties and risks, including, but not limited to, the following:

- required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with anti-bribery laws, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- political and economic instability,
- foreign exchange controls; and
- difficulties protecting or procuring intellectual property rights.

With respect to our international operations, our results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

Provisions in our Articles of Incorporation, Bylaws and Nevada law might decrease the chances of an acquisition.

Provisions of our Articles of Incorporation and Bylaws and applicable provisions of Nevada law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Some of the following provisions in our Articles of Incorporation or Bylaws that may decrease our attractiveness to be acquired are:

- advance notice of business to be brought is required for a meeting of our stockholders;
- the affirmative vote of the holders of at least sixty-six and two-thirds percent of the Company's outstanding voting power is required for stockholders to amend our Bylaws;
- stockholders are prohibited from requesting or calling a special meeting of stockholders;
- no cumulative voting rights for the holders of common stock in the election of directors; and
- vacancies in the board of directors may be filled by a majority vote of the directors then in office or by a sole remaining director, in either case though less than a quorum.

In addition, Section 78.438 of the Nevada Revised Statutes prohibits a publicly-held Nevada corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 10% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Regulatory Risks

We are subject to extensive governmental regulation, including the FDA.

We and our products, our suppliers, and our contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

- warning letters,
- fines and other monetary penalties,

- unanticipated expenditures,
- product recall or seizure,
- interruption of manufacturing,
- operating restrictions,
- injunctions, and
- criminal prosecutions.

In addition to the approval and clearance requirements, numerous other regulatory requirements apply to us and our products, our suppliers and contract manufacturers. These include requirements related to the following:

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

We are also subject to inspection by the FDA and other international regulatory bodies to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA and other international regulatory bodies will not identify compliance issues that may disrupt production or distribution or require substantial resources to correct.

The FDA's requirements and international regulatory body requirements may change, and additional regulations may be promulgated that could affect us, our products, and our suppliers and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

Regulatory approval of our products may be withdrawn at any time.

After regulatory approval has been obtained for medical device products, the product and the manufacturer are subject to continual review, including the review of adverse experiences and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturing facilities we use to make any of our products will also be subject to periodic review and inspection by the FDA or other regulatory authorities, as applicable. The discovery of any new or previously unknown problems with the product or facility may result in restrictions on the product or facility, including withdrawal of the product from the market. We will continue to be subject to the FDA or other regulatory authority requirements, as applicable, governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our products, even those that the FDA or other regulatory authority, as applicable, had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

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

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our approved products. The efficacy, safety, performance, and cost-effectiveness of our products, and of any competing products will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data,

which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our approved products in the international markets in which those pricing approvals are sought.

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

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

International sales of our products that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our products in markets outside the United States will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging, and labeling requirements, and import restrictions on medical devices. In addition, each country has its own tariff regulations, duties, and tax requirements. The approval by foreign government authorities is unpredictable and uncertain and can be expensive. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

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

Uncertainty surrounding and future changes to healthcare law in the United States may have a material adverse effect on us.

The healthcare regulatory environment in the United States is currently subject to significant uncertainty and the industry may in the future continue to experience fundamental change because of regulatory reform. From time to time, legislation is drafted and introduced in the United States Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture, marketing, and pricing of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. We could experience an adverse impact on our operating results due to such changes, including increased pricing pressure in these markets. Governments, hospitals, and other third-party payers also could reduce the amount of approved reimbursement for our products or deny coverage altogether. Reductions in reimbursement levels or coverage or other cost-containment measures could adversely affect our future operating results.

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

A provision of the Social Security Act, commonly referred to as the Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation, or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other Federal healthcare program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws like the Federal Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by Federal healthcare programs, but instead apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in Federal healthcare programs.

Our operations may also implicate the False Claims Act. If we fail to comply with Federal and state documentation, coding, and billing rules, we could be subject to liability under the Federal False Claims Act, including criminal and/or civil penalties, loss of licenses and exclusion from the Medicare and Medicaid programs. The False Claims Act prohibits

individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government.

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

Failure to comply with the HIPAA and state-specific privacy laws, as such rules become applicable to our business, may increase our operational costs.

The HIPAA privacy and security regulations establish comprehensive Federal standards with respect to the uses and disclosures of PHI by certain entities, including health plans and health care providers, and set standards to protect the confidentiality, integrity, and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including, for example: the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient; a patient's right to access, amend and receive an accounting of certain disclosures of PHI; the content of notices of privacy practices describing how PHI is used and disclosed and individuals' rights with respect to their PHI; and implementation of administrative, technical and physical safeguards to protect privacy and security of PHI. We anticipate that, as we expand our business, we will in the future be a covered entity under HIPAA. There can be no assurance that our policies and procedures will be adequate or will prevent all incidents of non-compliance with such regulations.

The HITECH Act and its implementing regulations also require healthcare providers to notify affected individuals, the Secretary of the U.S. Department of Health and Human Services, and in some cases, the media, when PHI has been breached as defined under and following the requirements of HIPAA. Many states have similar breach notification laws. In the event of a breach, to the extent such regulations are applicable to our business, we could incur operational and financial costs related to remediation as well as preparation and delivery of the notices, which costs could be substantial. Additionally, HIPAA, the HITECH Act, and their implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, private parties may also seek damages under state laws for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, amendments to HIPAA provide that the state attorneys general may bring an action against a covered entity for a violation of HIPAA. As we expand our business such that Federal laws regarding PHI and privacy apply to our operations, any noncompliance with such regulations could have a material adverse effect on our business, results of operations and financial condition.

In addition to our obligations under HIPAA, many states have laws that govern the processing, collection, use, disclosure, transfer, storage, disposal and protection of health-related and other sensitive and personal information. These state law protections are different and, in some cases, may be more stringent, broader in scope, or offer greater individual rights with respect to sensitive health information than HIPAA. These laws are evolving rapidly and may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. In addition to the state comprehensive data privacy laws, recent years have brought substantial changes to the federal and state treatment of non-HIPAA consumer health information. At the federal level, the FTC brought three enforcement actions in 2023 against a range of companies that handle electronic health information relating to collection and disclosure of non-HIPAA covered consume health information under Section 5 of the FTC Act, two of which included allegations made under the FTC's HBNR. The FTC's focus on health information continued in 2024 with changes to the HBNR that clarified its scope and emphasized applicability to non-HIPAA health care providers as well as three additional enforcement actions against companies for their use of health information for advertising purposes. On the state level, Washington and Nevada have adopted significant new legislation addressing businesses treatment of consumer health information, and Connecticut added more stringent protections for health information to its existing comprehensive state privacy law. In both Washington and Nevada's laws, there are restrictive provisions limiting collection and disclosure of consumer health information, and

Washington's law provides a separate private right of action for violations. Any noncompliance with applicable laws or regulations could have a material adverse effect on our business, results of operations and financial condition.

We face periodic reviews and billing audits from governmental and private payors, and these audits could have adverse results that may negatively impact our business.

As a result of our participation in the Medicare and Medicaid programs, we are subject to various governmental reviews and audits to verify our compliance with these programs and applicable laws and regulations. We also are subject to audits under various government programs in which third-party firms engaged by the CMS conduct extensive reviews of claims data and medical and other records to identify potential improper payments under the Medicare program. Private pay sources also reserve the right to conduct audits. If billing errors are identified in the sample of reviewed claims, the billing error can be extrapolated to all claims filed, which could result in a larger overpayment than originally identified in the sample of reviewed claims. Our costs to respond to and defend reviews and audits may be significant and could have a material adverse effect on our business, financial condition, results of operations and cash flows. Moreover, an adverse review or audit could result in:

- required refunding or retroactive adjustment of amounts we have been paid by governmental or private payors;
- state or Federal agencies imposing fines, penalties and other sanctions on us;
- loss of our right to participate in the Medicare program, state programs, or one or more private payor networks; or
- damage to our business and reputation in various markets.

Any one of these results could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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

Risks Related to Intellectual Property

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

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

- obtain and/or maintain protection for our products under the patent laws of the United States and other countries;
- defend and enforce our patents once obtained;
- obtain and/or maintain appropriate licenses to patents, patent applications or other proprietary rights held by others with respect to our technology, both in the United States and other countries;

- maintain trade secrets and other intellectual property rights relating to our products; and
- operate without infringing upon the patents, trademarks, copyrights, and proprietary rights of third parties.

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

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

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

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

The patent applications that we own and that have been licensed to us, and any future patent applications that we may own or that may be licensed to us, may not result in the issuance of any patents. The standards that the United States Patent & Trademark Office and foreign patent agencies use to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to the type and scope of patent claims to which we may in the future be entitled under our license agreements or that may be issued to us. These applications may not be sufficient to meet the

statutory requirements for patentability and, therefore, may not result in enforceable patents covering the products we want to commercialize. Further, patent applications in the United States that are not filed in other countries may not be published or generally are not published until at least 18 months after they are first filed, and patent applications in certain foreign countries generally are not published until many months after they are filed. Scientific and patent publication often occurs long after the date of the scientific developments disclosed in those publications. As a result, we cannot be certain that we will be the first creator of inventions covered by our patents or applications, or the first to file such patent applications. As a result, our issued patents and our patent applications could become subject to challenge by third parties that created such inventions or filed patent applications before us or our licensors, resulting in, among other things, interference proceedings in the United States Patent & Trademark Office to determine priority of discovery or invention. Interference proceedings, if resolved adversely to us, could result in the loss of or significant limitations on patent protection for our products or technologies. Even in the absence of interference proceedings, patent applications now pending or in the future filed by third parties may prevail over the patent applications that may be owned by us or licensed to us or that we may file in the future, or may result in patents that issue alongside patents issued to us or our licensors or that may be issued or licensed to us in the future, leading to uncertainty over the scope of the patents owned by us or licensed to us or that may in the future be owned by us or impede our freedom to practice the claimed inventions.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Common Stock

Our stock price is volatile.

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

- our ability to obtain additional financing and, if available, the terms and conditions of the financing;
- changes in our industry;

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

Our management and Board of Directors (the "Board") recognize the importance of maintaining the security and resiliency of our cybersecurity environment to deliver on the expectations of our customers, business partners, employees, and investors. The Board is involved in our risk management practices. Overall, the purpose of our information security program is to protect the confidentiality, integrity and availability of our systems and data, along with the safe operation of our systems.

Technical safeguards

We deploy technical safeguards that are designed to protect our systems from cybersecurity threats, including firewalls, anti-malware software, and authentication and authorization controls.

Security awareness and training

We provide ongoing security awareness and training to educate internal users on how to identify and report potential issues. Phishing emails are discussed on a regular basis with employees to ensure proper protocols are followed. We also provide periodic updates to employees on emerging cybersecurity trends and ways to protect themselves and the Company.

Governance of Cybersecurity Risks

The Audit Committee of the Board has the primary responsibility for oversight, review and discussion with management of the Company's information technology, data security, business continuity, artificial intelligence, and cybersecurity-related risk exposures and threats; the potential impact of those risk exposures and threats on the Company's business, operations and reputation; and the processes management has established to assess, manage, monitor, and mitigate such risk exposures and threats. The Company's Chief Executive Officer and Chief Financial Officer are responsible for assessing and managing cybersecurity risks. The Company's management periodically reports on cybersecurity issues and presents information to our Audit Committee as well as our full Board, as appropriate, on cybersecurity matters.

Upon verifying that a cybersecurity incident has occurred or is occurring, the Chief Executive Officer and Chief Financial Officer will promptly conduct a preliminary assessment of the severity level of the cybersecurity incident. Following this assessment, the Chief Executive Officer will determine whether to report the cybersecurity incident to the Audit Committee, who will then report such cybersecurity incident to the Board as the chair deems appropriate.

Material Impact of Cybersecurity Risks

We have not experienced a material information security breach incident, and we are not aware of any cybersecurity risks that are reasonably likely to materially affect our business. However, future incidents could have a material impact on our business strategy, results of operations or financial condition. For additional discussion of the risks posed by cybersecurity threats, see "Item 1A. Risk Factors— Risks to our Business— *We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage*."

Item 2. PROPERTIES

Our primary corporate and operations office is a leased facility in Eden Prairie, Minnesota, consisting of 20,019 square feet of space under a lease which expires on August 31, 2030. Under the terms of the lease, we pay monthly rent, subject to a 3.5% adjustment on an annual basis.

Item 3. LEGAL PROCEEDINGS

In the ordinary course of business, the Company from time to time becomes involved in various legal proceedings involving a variety of matters. We do not believe there are any pending legal proceedings that will have a material adverse effect on our 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.

There are no material proceedings known to us to be contemplated by any governmental authority.

There are no material proceedings known to us, pending, or contemplated, in which any of our directors, officers or affiliates or any of our principal security holders, or any associate of any of the foregoing, is a party or has an interest adverse to us.

Item 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

The Company's common stock is quoted on the Nasdaq Global Market under the symbol "SNWV".

Holders of Common Stock

As of March 24, 2026, there were 8,594,209 shares of common stock outstanding and approximately 159 holders of record of the Company's common stock.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, current and anticipated capital requirements, business prospects, and other factors our board of directors deems relevant, and subject to applicable laws and the restrictions contained in any future financing instruments.

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations provides information management believes to be relevant to understanding the financial condition and results of operations of the Company. The discussion focuses on our financial results of operations for the years ended December 31, 2025 and 2024. You should read this discussion and analysis in conjunction with our consolidated financial statements and related notes thereto for the years ended December 31, 2025, and 2024, which are presented within Part II, Item 8. "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. This discussion has been updated to reflect the restatement of our previously issued financial statements for the quarters ended March 31, June 30, September 30, 2025, and the year ended 2024. All amounts and discussions herein are based on the restated financial information. Refer to Note 2 to the consolidated financial statements for further details regarding the nature and impact of the restatement. Amounts reported in thousands within this annual report are computed based on the amounts in thousands, and therefore, the sum of the components may not equal the total amount reported in thousands due to rounding.

Executive Summary

We realized significant revenue growth during the year ended December 31, 2025, with a 35% growth in revenue to $44.1 million for the year ended December 31, 2025, as compared to $32.6 million in 2024. Gross margins also increased to 77% from 75% in 2024. As the Company continues to focus on profitable growth, we have also increased our operating income by 29% to $4.9 million for the year ended December 31, 2025, compared to $3.8 million for the year ended December 31, 2024.

Net income for the year ended December 31, 2025, was $11.8 million, or $1.38 per basic share and $0.41 per diluted share, compared to a net loss of $33.1 million, or $7.41 per basic and diluted share, for the year ended December 31, 2024, an increase of $44.9 million, which was largely driven by a non-cash change in the fair value of derivatives and improved operational performance. We believe these improvements set the stage for additional growth as we head into 2026.

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 income (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 GAAP to Non-GAAP Reconciliations section below, our non-GAAP financial measures exclude the impact of certain charges that contribute to our net income (loss).

(in thousands)	For the Years Ended December 31, 2025	2024 (As Restated)
Net Income (Loss)	$ 11,813	$ (33,083)
Non-GAAP Adjustments:		
Interest expense	6,246	13,779
Depreciation and amortization	1,265	1,145
EBITDA	$ 19,324	$ (18,159)
Non-GAAP Adjustments for Adjusted EBITDA:		
Change in fair value of derivative liabilities	(8,107)	31,413
Other non-cash or infrequent charges:		
Stock-based compensation	4,850	1,514
Loss (Gain) on extinguishment of debt	477	(6,326)
Loss on impairment of assets	196	-
Severance agreement and legal settlement	202	741
Release of historical accrued expenses	-	(1,547)
Gain on license and option agreement	(5,000)	(2,500)
Prepaid legal fees expensed from termination of Merger Agreement	-	457
State and local sales tax [1]	1,567	1,569
Sale and disposal of PACE product line [2]	123	-
Adjusted EBITDA	$ 13,632	$ 7,162

[1] The charges represent a non-recurring state and local sales tax expense related to the restatement of prior period financial statements.

[2] The charges represent the net amount of proceeds received of $0.4 million and inventory written down of $0.5 million, as part of the Company's sale and disposal of the PACE product line.

Results of Operations

The following table sets forth our consolidated statement of operations:

(in thousands)	For the Years Ended December 31, 2025	2024 (As Restated)	Change $	Change %
Revenue	$ 44,051	$ 32,634	$ 11,417	35%
Cost of revenue	10,082	8,084	1,998	25%
Gross margin	33,969	24,550	9,419	38%
Gross margin %	77%	75%		
Operating expenses:				
General and administrative	19,372	12,917	6,455	50%
Selling and marketing	7,419	6,323	1,096	17%
Research and development	1,353	673	680	101%
Depreciation and amortization	880	789	91	12%
Operating Income	4,945	3,848	1,097	29%
Total Other Income (Expense)	6,954	(36,904)	43,858	119%
Income tax expense	86	27	59	219%
Net Income (Loss)	$ 11,813	$ (33,083)	$ 44,896	136%

Revenue

Revenues for the year ended December 31, 2025 were $44.1 million, compared to $32.6 million for 2024, an increase of $11.4 million or 35%. The increase in revenue was primarily driven by higher sales volumes of UltraMIST® consumables and systems. The quantity of UltraMIST® consumables sold increased 24%, and UltraMIST® systems sold increased by 67% in 2025 compared to 2024.

Pricing trends also contributed to year-over-year performance. The average selling price of UltraMIST® consumables increased 3% in 2025 compared to 2024. In contrast, the average selling price of UltraMIST® systems declined by 3%, primarily due to a higher proportion of sales through resellers. UltraMIST® systems sold through resellers comprised 34% of system sales in 2025 compared to no reseller system sales in 2024. Expanding reseller sales supports faster placement of systems into customer facilities and contributes to growth in our active system base.

Cost of Revenue

Cost of revenues for the year ended December 31, 2025 were $10.1 million, compared to $8.1 million for 2024. Gross profit as a percentage of revenues was 77% for the year ended December 31, 2025, compared to 75% for the same period in 2024. This increase in gross margin was largely driven by increased pricing on our UltraMIST® consumables and reductions in system cost of revenue, partially offset by a decrease in UltraMIST® system pricing, largely resulting from a higher reseller mix. The average gross profit of systems sold increased 0.1% in 2025 compared to 2024.

General and Administrative

General and administrative expenses for the year ended December 31, 2025 were $19.4 million as compared to $12.9 million for 2024, an increase of $6.5 million, or 50%. The increase in 2025 as compared to 2024 was primarily due to increased headcount expenses of $2.7 million, non-cash charges for stock-based compensation totaling $2.4 million, software expenses of $0.4 million, audit and tax professional expenses of $0.2 million, and public company costs of $0.2 million.

Selling and Marketing

Selling and marketing expenses for the year ended December 31, 2025 were $7.4 million as compared to $6.3 million for 2024, an increase of $1.1 million, or 17%. The year-over-year increase in sales and marketing expenses in 2025, was primarily driven by increased headcount expenses of $1.9 million, non-cash charges for stock-based compensation totaling $0.8 million, and consulting expenses of $0.5 million, partially offset by a decrease in outside commission expense of $1.9 million as our focus shifted toward a higher mix of resellers versus distributors.

Research and Development

Research and development expenses for the year ended December 31, 2025 were $1.4 million, compared to $0.7 million for 2024. The increase in research and development costs in 2025 as compared to 2024, was largely driven by research and development (R&D) project expenses totaling $0.2 million, consulting expenses of $0.2 million, and patent legal fees of $0.2 million.

Other Income (Expense), net

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

	For the Years Ended December 31,		Change	
	2025	2024 (As Restated)	$	%
Interest expense	$ (6,246)	$ (13,779)	$ 7,533	(55%)
(Loss) Gain on extinguishment of debt	(477)	6,326	(6,803)	(108%)
Change in fair value of derivative liabilities	8,107	(31,413)	39,520	126%
Loss on impairment of assets	(196)	-	(196)	-%
Other expense	(42)	(893)	851	(95%)
Other income	5,808	2,855	2,953	103%
Total Other Income (Expense)	$ 6,954	$ (36,904)	$ 43,858	(119%)

Total other income for the year ended December 31, 2025 was $7.0 million, as compared to an expense of $36.9 million for 2024, an increase of $43.9 million. The increase was primarily driven by the change in fair value of derivative liabilities of $39.5 million, interest expense reduction of $7.5 million, and an other income increase of $3.0 million, partially offset by a change in the gain (loss) on extinguishment of debt of $6.8 million. The change in fair value of derivative liability relates to the valuation of warrants previously issued by the Company. The reduction in interest expense is due to the conversion of previously issued notes that were exchanged for common stock in October 2024 as described in Note 13 of our consolidated financial statements, as well as a reduction in interest rate from the repayment of our Senior Secured Debt and issuance of our Term Loan as described in Note 9 of our consolidated financial statements. Other income for 2025 mainly consists of the one-time payment of $5.0 million related to the patent purchase agreement as described in Note 20 of our consolidated financial statements. Other income for 2024 mainly consists of the one-time payment of $2.5 million related to the Patent License agreement as described in Note 20 of our consolidated financial statements.

Liquidity and Capital Resources

From inception through the year ended December 31, 2024, we incurred losses from operations each year. As of December 31, 2025, we had an accumulated deficit of $242.7 million. Historically, our operations have primarily been funded from the sale of capital stock, and issuances of notes payable, and convertible debt securities.

We have incurred recurring net losses in prior years, currently have a significant accumulated deficit, and have experienced negative working capital. Previously, the scheduled maturity of the Senior Secured debt in September 2025 raised substantial doubt about our ability to continue as a going concern for a period of 12 months from the filing of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025.

However, as described in Note 9 of our consolidated financial statements, we successfully refinanced our outstanding debt during 2025. The refinancing extended the maturity of our debt and provided the option for additional liquidity to support ongoing operations through the secured revolving credit facility. In addition, the operating income achieved in 2025, the receipt of $5.0 million from the patent purchase agreement as described in Note 20 of our consolidated financial statements, and the capital raised from a private placement in October 2024 as described in Note 14 of our consolidated financial statements, have all contributed to a significant improvement in our financial position.

Management has evaluated our ability to continue as a going concern in light of these developments. Based on the successful refinancing and other recent initiatives, management believes the Company has sufficient resources to meet its obligations as they become due and to continue as a going concern for at least the next 12 months. We continue to monitor our financial position, liquidity, and compliance with debt covenants on an ongoing basis.

Management remains focused on maintaining the Company's improved financial position and operational momentum. While we continue to monitor our liquidity and capital resources closely, we believe that the successful refinancing of our debt, as described in Note 9 of our consolidated financial statements, together with our recent operating income and capital initiatives, have significantly strengthened our ability to meet our obligations as they come due. These actions have alleviated the substantial doubt about our ability to continue as a going concern. We will continue to evaluate opportunities to further enhance our capital structure and support our growth strategy. Although we cannot predict all future events or guarantee that unforeseen circumstances will not arise, we are confident that the steps taken to date position the Company well to support ongoing operations and execute on our strategic objectives.

The following table presents summarized cash flow information:

	For the years ended December 31,	
(in thousands)	2025	2024 (As Restated)
Cash flows provided by operating activities	$ 3,876	$ 2,455
Cash flows provided by (used in) investing activities	$ 3,433	$ (490)
Cash flows (used in) provided by financing activities	$ (5,587)	$ 6,354

Cash Flows from Operating Activities

Cash provided by operating activities for 2025 totaled $3.9 million. The primary source was net income of $11.8 million, adjusted for non-cash items including stock-based compensation expense of $4.9 million, amortization of debt issuance costs and debt discounts of $1.5 million, depreciation and amortization of $1.3 million, a $0.5 million inventory write-off related to the disposal of PACE, $0.6 million in tenant improvement allowances received, and $0.9 million of other non-cash items. These were partially offset by a non-cash gain of $8.1 million on the change in fair value of derivative liabilities, a $5.4 million non-cash gain on the sale of patents, and a $4.0 million net use of cash from changes in operating assets and liabilities, driven primarily by an increase in accounts receivable reflecting higher revenue activity and an increase in inventory due to a build up to support anticipated demand.

Cash provided by operating activities for 2024 totaled $2.5 million and consisted primarily of the change in fair value of derivative liabilities connected to our convertible debt and warrants issued. The Company recognized a loss on these liabilities of $31.4 million for the year ended December 31, 2024.

Cash Flows from Investing Activities

Cash provided by investing activities for 2025 totaled $3.4 million, consisting of $5.4 million in proceeds from the sale of patents, partially offset by $1.9 million in purchases of property and equipment.

Cash used in investing activities for 2024 totaled $0.5 million, consisting entirely of purchases of property and equipment.

Cash Flows Provided by Financing Activities

Cash used in financing activities for 2025 totaled $5.6 million, consisting primarily of $27.7 million in payments on notes payable, $1.4 million in repayment of principal on the secured term loan, $0.4 million in debt issuance costs, and $0.2 million in principal payments on finance leases, partially offset by $23.0 million in proceeds from a new secured term loan,

$0.7 million in proceeds from the secured revolving credit facility, and $0.6 million in proceeds from exercises of stock options.

Cash provided by financing activities for 2024 totaled $6.4 million, consisting primarily of $10.3 million in proceeds from the sale of common stock, $1.3 million in proceeds from convertible promissory notes, and $0.5 million from secured promissory notes payable from a related party, partially offset by $3.5 million in payments on notes payable, $0.5 million in repayments of secured promissory notes payable to a related party, $1.5 million in payments to factoring, and $0.2 million in principal payments on finance leases.

Critical Accounting Estimates

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations.

Management has discussed the development and selection of these critical accounting estimates with the Audit Committee of our Board of Directors. In addition, there are other items within our consolidated financial statements that require estimation, but are not deemed critical as defined above. Changes in estimates used in these and other items could have a material impact on our consolidated financial statements.

We have used various accounting policies to prepare the 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 this Annual Report on Form 10-K.

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

The following accounting estimates are deemed critical:

Litigation Contingencies

We may be involved in legal actions involving product liability, intellectual property and commercial disputes, tax disputes, and governmental proceedings and investigations. The outcomes of these legal actions are not completely within our control and may not be known for prolonged periods of time. In some actions, the enforcement agencies or private claimants seek damages that could require significant expenditures or result in lost revenues or limit our ability to conduct business in the applicable jurisdictions. Estimating probable losses from our litigation and governmental proceedings is inherently difficult, particularly when the matters are in early procedural stages, with incomplete scientific facts or legal discovery; involve unsubstantiated or indeterminate claims for damages; potentially involve penalties, fines, or punitive damages; or could result in a change in business practice. The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable, and the amount may be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed. Our significant legal proceedings are discussed in Note 21 to the consolidated financial statements in Part II, Item 8. “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

Sales Tax Nexus and Related Liabilities

During the fiscal year ended December 31, 2025, the Company completed its initial sales tax nexus study to evaluate its obligations to collect and remit sales tax across various state and local jurisdictions. Determining the extent of the Company's sales tax nexus requires significant judgment regarding the nature of the Company's business activities in each jurisdiction, the applicability of economic nexus thresholds, specific customers and their exempt status, the interpretation of

state and local tax laws and regulations, which continue to evolve following South Dakota v. Wayfair, Inc. and subsequent legislative developments. This can cause changes in the widely acceptable administrative practices of jurisdictions.

The Company recorded a liability for estimated sales tax obligations, including potential interest and penalties, arising from both current and prior periods, when an exposure is considered probable and the amount can be reasonably estimated. Where the reasonable estimate of a probable liability is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. Reasonably possible exposures identified in the study that do not meet the threshold for accrual are disclosed when material. Given the inherent complexity of multistate tax compliance and the application of economic nexus rules, actual liabilities may differ materially from current estimates, depending on the outcome of ongoing or future reviews by state tax authorities. Such differences may have a material impact on the Company's financial condition, results of operations, or cash flows.

Segment and Geographic Information

We have determined that we have one reportable segment. Our revenues are generated from sales primarily in the United States. 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 reportable segment, refer to Note 22 to the consolidated financial statements.

Effects of Inflation

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.

Recently Issued Accounting Standards

Information regarding new accounting pronouncements is included in Note 3 to the consolidated financial statements in Part II, Item 8. “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

Item 7A. 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of SANUWAVE Health, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of SANUWAVE Health, Inc. (the "Company") as of December 31, 2025, the related consolidated statements of comprehensive income (loss), stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
March 26, 2026

We have served as the Company's auditor since 2025.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
SANUWAVE Health, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of SANUWAVE Health, Inc. (the "Company") and Subsidiaries as of December 31, 2024, the related consolidated statements of comprehensive income (loss), stockholders' equity (deficit), and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Restatement of December 31, 2024 Financial Statements

As discussed in Note 2 to the financial statements, the accompanying financial statements as of and for the year ended December 31, 2024, have been restated to correct misstatements regarding accounting for state sales and use tax liability.

Explanatory Paragraph – Going Concern

The 2024 financial statements were prepared assuming that the Company would continue as a going concern. As of the date of the issuance of the 2024 financial statements, the Company had incurred recurring losses, had negative working capital, and needed to refinance its debt to meet its obligations and sustain its operations. These conditions raised substantial doubt about the Company's ability to continue as a going concern as of the date of the issuance of the 2024 financial statements. The 2024 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We served as the Company's auditor from 2018 to 2025.

New York, NY
March 20, 2025, except for the effects of the restatement as discussed in Note 2 to the consolidated financial statements, as to which the date is March 26, 2026

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2025 and 2024

(In thousands, except share data)	2025	2024 (As Restated)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,959	$ 10,237
Accounts receivable, net of allowance of $1,265 and $1,147, respectively	5,422	3,329
Inventory	5,934	4,149
Prepaid expenses and other current assets	1,312	682
Total Current Assets	24,627	18,397
Non-Current Assets:		
Property and equipment, net	1,972	303
Right of use assets, net	390	429
Intangible assets, net	3,026	3,730
Goodwill	7,260	7,260
Secured revolving credit facility debt issuance costs, net	68	-
Total Non-Current Assets	12,716	11,722
Total Assets	$ 37,343	$ 30,119
LIABILITIES		
Current Liabilities:		
Current portion of secured term loan	$ 5,638	$ -
Senior secured debt	-	25,305
Accounts payable	3,251	3,728
Accrued expenses	8,382	7,756
Warrant liability	-	8,107
Current portion of operating lease liabilities	157	126
Current portion of finance lease liabilities	-	175
Current portion of contract liabilities	388	193
Accrued interest	24	-
Other	7	33
Total Current Liabilities	17,847	45,423
Non-Current Liabilities:		
Secured term loan, net of current portion and debt issuance costs	15,667	-
Secured revolving credit facility	655	-
Operating lease liabilities, less current portion	854	125
Finance lease liabilities, less current portion	-	66
Contract liabilities, less current portion	701	300
Total Non-Current Liabilities	17,877	491
Total Liabilities	35,724	45,914
Commitments and Contingencies (Note 21)		

STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, par value $0.001, 5,000,000 shares authorized, 6,175 Series A, 293 Series B, 90 Series C, and 8 Series D designated shares, respectively; no shares issued and outstanding at December 31, 2025 and 2024	-	-
Common stock, par value $0.001, 2,500,000,000 shares authorized, 8,588,876 and 8,543,686 issued and outstanding at December 31, 2025 and 2024, respectively	9	9
Additional paid-in capital	244,285	238,685
Accumulated deficit	(242,685)	(254,499)
Accumulated other comprehensive loss	10	10
Total Stockholders' Equity (Deficit)	1,619	(15,795)
Total Liabilities and Stockholders' Equity (Deficit)	$ 37,343	$ 30,119

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
Years ended December 31, 2025 and 2024

(In thousands, except share and per share data)	2025	2024 (As Restated)
Revenue	$ 44,051	$ 32,634
Cost of revenues	10,082	8,084
Gross Margin	33,969	24,550
Operating Expenses:		
General and administrative	19,372	12,917
Selling and marketing	7,419	6,323
Research and development	1,353	673
Depreciation and amortization	880	789
Total Operating Expenses	29,024	20,702
Operating Income	4,945	3,848
Other Income (Expense)		
Interest expense	(6,246)	(12,565)
Interest expense, related party	-	(1,214)
(Loss) Gain on extinguishment of debt	(477)	6,326
Change in fair value of derivative liabilities	8,107	(31,413)
Loss on impairment of assets	(196)	-
Other expense	(42)	(893)
Other income (See Note 20)	5,808	2,855
Total Other Income (Expense)	6,954	(36,904)
Net Income (Loss) Before Income Taxes	11,899	(33,056)
Income tax expense	86	27
Net Income (Loss)	$ 11,813	$ (33,083)
Other Comprehensive Income (Loss)		
Foreign currency translation adjustments	-	121
Total Comprehensive Income (Loss)	$ 11,813	$ (32,962)
Earnings (Loss) per Share:		
Basic	$ 1.38	$ (7.41)
Diluted	$ 0.41	$ (7.41)
Weighted average shares outstanding:		
Basic	8,563,510	4,462,883
Diluted	9,082,510	4,462,883

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

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

	Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance as of December 31, 2023 (as previously reported)	3,041,492	$ 3	$ 176,979	$ (220,049)	$ (111)	$ (43,178)
Correction of prior period error (See Note 2)	-	-	-	(1,367)	-	(1,367)
Balance as of January 1, 2024 (as restated)	3,041,492	$ 3	$ 176,979	$ (221,416)	$ (111)	$ (44,545)
Sale of common stock	1,248,489	1	10,299	-	-	10,300
Shares issued for settlement of warrants	3,558,396	4	41,380	-	-	41,384
Shares issued for settlement of debt	685,737	1	8,513	-	-	8,514
Stock-based compensation	9,572	-	1,514	-	-	1,514
Foreign currency translation adjustment			-	-	121	121
Net loss (as restated)		-	-	(33,083)	-	(33,083)
Balance as of December 31, 2024 (as restated)	8,543,686	$ 9	$ 238,685	$ (254,499)	$ 10	$ (15,795)
Stock-based compensation	4,787	-	4,968	-	-	4,968
Stock options exercised	37,879	-	555	-	-	555
Shares granted in lieu of board of director fees	2,524	-	77	-	-	77
Net income	-	-	-	11,813	-	11,813
Balance as of December 31, 2025	8,588,876	$ 9	$ 244,285	$ (242,685)	$ 10	$ 1,619

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2025 and 2024

(In thousands)	2025	2024 (As Restated)
Operating Activities		
Net income (loss)	$ 11,813	$ (33,083)
Adjustments to reconcile net income (loss) to net cash provided by operating activities		
Stock-based compensation	4,850	1,514
Depreciation and amortization	974	788
Amortization of right-of-use assets	309	357
Provision for credit losses	202	77
Loss on disposal and impairment of assets	210	-
Loss (gain) on extinguishment of debt	477	(6,326)
Change in fair value of derivative liabilities	(8,107)	31,413
Gain on sale of patents	(5,375)	-
Amortization of debt issuance and debt discounts	1,461	5,520
Write-off of inventory related to PACE disposal	498	-
Gain on lease modification	(7)	-
Accrued interest and accrued interest, related parties	-	3,387
Proceeds from tenant improvement funds	586	-
Changes in operating assets and liabilities		
Accounts receivable	(2,296)	(486)
Inventory	(2,283)	(1,198)
Prepaid expenses and other assets	(724)	(79)
Accounts payable	(521)	(1,422)
Accrued expenses and contract liabilities	1,965	1,993
Operating leases	(156)	-
Net Cash Provided by Operating Activities	3,876	2,455
Investing Activities		
Purchases of property and equipment	(1,942)	(490)
Proceeds from sale of patents	5,375	-
Net Cash Provided by (Used in) Investing Activities	3,433	(490)
Financing Activities		
Repayment of principal secured term loan	(1,438)	-
Proceeds from secured term loan	23,000	-
Proceeds from secured revolving credit facility	655	-
Payment of debt issuance costs	(371)	-
Proceeds from exercises of stock options	556	-
Payment of note payable	(27,747)	(3,548)
Proceeds from convertible promissory notes	-	1,300
Proceeds from secured promissory notes payable, related party	-	500
Payments to secured promissory notes payable, related party	-	(500)

Proceeds from sale of common stock	-	10,300
Payments to factoring	-	(1,490)
Principal payments on finance leases	(242)	(208)
Net Cash (Used in) Provided by Financing Activities	(5,587)	6,354
Effect of Exchange Rates on Cash and Cash Equivalents	-	121
Net Change in Cash and Cash Equivalents During Period	1,722	8,440
Cash and Cash Equivalents at Beginning of Period	10,237	1,797
Cash and Cash Equivalents at End of Period	$ 11,959	$ 10,237
Supplemental Information:		
Cash paid for interest	$ 3,744	$ 4,311
Cash paid for state income taxes	27	4
Non-Cash Investing and Financing Activities:		
Capitalize default interest into senior secured debt	$ 549	$ 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	-
Lease liabilities reduced upon lease modification	99	-
Purchases of property and equipment in accounts payable	45	-
RSUs granted in exchange for services	10	-
Shares issued for settlement of debt	-	8,513
Write off deferred merger costs	-	1,225
Warrants issued in conjunction with senior secured promissory note payable and convertible promissory notes payable	-	3,557
Conversion of warrants to common stock	-	41,380
Conversion of asset-based secured promissory notes to convertible promissory notes	-	4,584

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

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. Sanuwave was founded in 2004 and is headquartered in Eden Prairie, Minnesota.

Basis of Presentation - The accompanying 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") and with the instructions to Form 10-K and Regulation S-X. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. Amounts reported in thousands within this annual report are computed based on the amounts in thousands, and therefore, the sum of the components may not equal the total amount reported in thousands due to rounding.

Use of Estimates - The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Foreign Currency Translation - The functional currencies of the Company's foreign operations are their local currencies. The financial statements of the Company's foreign subsidiary have been translated into United States dollars. All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. Translation adjustments are reported in other comprehensive income (loss) in the consolidated statements of comprehensive income (loss) and as cumulative translation adjustments in accumulated other comprehensive loss in the consolidated balance sheets.

Reverse Stock Split - All share numbers, including the number of shares underlying warrants, options, and convertible debt, and per share amounts presented in these 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 consolidated balance sheets and statement of cash flows have been reclassified to conform to the presentation of the current year consolidated financial statements. These reclassifications had no effect on the previously reported operating results.

2. Restatement of Previously Issued Financial Statements

In connection with the preparation of the Company's consolidated financial statements for the year ended December 31, 2025, the Company engaged a specialist to conduct a sales and use tax nexus study. Management concluded that the Company had a historical state sales and use tax liability related to prior periods. The Company is required and subject to collect and remit sales and use tax in state and local jurisdictions where it has economic and physical nexus. During the year ended December 31, 2025, the Company determined that a sales tax liability existed and estimated a liability for sales transactions processed in jurisdictions where it had not previously reported.

The liability includes an estimate for each state, to account for any penalties and interest that is due on the base tax amount owed. The error resulted in an understatement of accrued expenses for state and local sales tax, including related interest and penalties, in the previously issued consolidated financial statements as of and for the year ended December 31, 2024 (refer to Note 24 for quarterly 2024 and 2025 impacts). As a result of correcting this liability, general and administrative expenses and interest expense were increased in the affected periods, resulting in a one-time, non-recurring increase in reported expenses for the year ended December 31, 2024. This adjustment reflects the cumulative impact of previously

unrecorded sales tax, interest, and penalties. The Company does not expect similar expense impacts to recur in future periods, as the underlying sales tax obligations have now been appropriately recognized and remediated.

Consolidated Financial Statements - Restatement Reconciliation Tables

In accordance with Accounting Standards Codification ("ASC") 250, *Accounting Changes and Error Corrections*, the Company has corrected this error by restating the prior period financial statements. The cumulative effect of the correction as of January 1, 2024, was a $1.4 million increase to accumulated deficit, as reflected in the consolidated statement of stockholders' equity (deficit). The impact of the correction on the Company's previously issued consolidated financial statements is summarized as follows:

Consolidated Balance Sheet - January 1, 2024 (opening):

(in thousands)	As of January 1, 2024		
Consolidated Balance Sheet	As Previously Reported	Adjustment	As Restated
Accrued expenses	$ 5,999	$ 1,367	$ 7,366
Total Liabilities	65,594	1,367	66,961
Accumulated Deficit	(220,049)	(1,367)	(221,416)
Total Stockholders' Deficit	$ (43,178)	$ (1,367)	$ (44,545)

The $1.4 million adjustment to accumulated deficit as of January 1, 2024, represents the cumulative effect of understated general and administrative expenses of $1.3 million and understated interest expense of $46 thousand recorded during prior years.

Consolidated Balance Sheet - December 31, 2024:

The amounts in the "As Restated" columns are the updated amounts including the impacts from the restatement. Financial statement line items and subtotals that were not impacted by the restatement adjustments have been omitted for enhanced clarity.

(in thousands)		As of December 31, 2024		
Consolidated Balance Sheet	Notes	As Previously Reported	Adjustment	As Restated
Accrued expenses	(i)	$ 4,678	$ 3,078	$ 7,756
Total Current Liabilities		42,345	3,078	45,423
Total Liabilities		42,836	3,078	45,914
Accumulated Deficit		(251,421)	(3,078)	(254,499)
Total Stockholders' Deficit		$ (12,717)	$ (3,078)	$ (15,795)

A description of the restatement adjustments in the consolidated balance sheets is as follows:

(i) The $3.1 million increase in accrued expenses as of December 31, 2024 is related to the accrued sales tax, and the related interest and penalties on outstanding sales tax balances through December 31, 2024.

Consolidated Statement of Comprehensive Loss - Year Ended December 31, 2024:

(in thousands, except per share data)		For the year ended December 31, 2024		
Consolidated Statement of Comprehensive Loss	Notes	As Previously Reported	Adjustment	As Restated
General and administrative	(i)	$ 11,348	$ 1,569	$ 12,917
Total Operating Expenses		19,133	1,569	20,702
Operating Income		5,417	(1,569)	3,848
Interest expense	(ii)	(12,423)	(142)	(12,565)
Total Other Expense		(36,762)	(142)	(36,904)
Net Loss Before Income Taxes		(31,345)	(1,711)	(33,056)
Net Loss		(31,372)	(1,711)	(33,083)
Total Comprehensive Loss		(31,251)	(1,711)	(32,962)
Net Loss per share: basic and diluted		$ (7.03)	$ (0.38)	$ (7.41)

A description of the restatement adjustments in the consolidated statement of comprehensive loss is as follows:

(i) The $1.6 million increase in general and administrative expenses is related to the adjustment for estimated state and local sales tax expense and for the related penalties on outstanding sales tax balances for the year ended December 31, 2024.

(ii) The $142 thousand increase in interest expense is related to the adjustment for estimated interest on outstanding state and local sales tax balances for the year ended December 31, 2024.

Consolidated Statements of Changes in Stockholders' Equity (Deficit):

The Consolidated Statement of Changes in Stockholders' Equity (Deficit) for 2024 in the accompanying consolidated financial statements has been restated to reflect the correction of prior period errors described above. The cumulative effect of errors originating in fiscal years prior to 2024 are presented as a discrete adjustment to the opening accumulated deficit balance as of January 1, 2024, rather than being allocated back to those individual years.

The line item "Correction of prior period error" presented in the Consolidated Statement of Changes in Stockholders' Equity (Deficit) represents the aggregate understatement of general and administrative expenses of $1.3 million and interest expense of $46 thousand originating in prior fiscal years, resulting in a cumulative increase to accumulated deficit of $1.4 million as of January 1, 2024 with no income tax effect due to the Company's full valuation allowance against its net deferred tax assets.

The accumulated deficit balance as of December 31, 2024, as restated, reflects both the cumulative opening adjustment of $1.4 million described above and the additional restatement adjustments of $1.7 million attributable to the understatement of general and administrative expenses and interest expense within fiscal year 2024. The combined effect of all restatement adjustments increased the Company's accumulated deficit by $3.1 million in the aggregate across all affected periods.

No other components of stockholders' equity (deficit), including common stock, additional paid-in capital, or other comprehensive income (loss), were affected by this restatement.

Consolidated Statement of Cash Flows - Year Ended December 31, 2024

The correction of these errors had no effect on the total cash flows from operations, investing, or financing of the Company.

(in thousands)		For the year ended December 31, 2024		
Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Loss		$ (31,372)	$ (1,711)	$ (33,083)
Accrued expenses and contract liabilities	(i)	282	1,711	1,993
Net Cash Provided by Operating Activities		$ 2,455	$ -	$ 2,455

Description of the restatement adjustments in the consolidated statement of cash flows is as follows:

(i) The $1.7 million increase in accrued expenses for the year ended December 31, 2024 is related to the accrued sales tax, and the related interest and penalties on outstanding sales tax balances.

Income Tax Effects

The Company maintains a full valuation allowance against its net deferred tax assets. Accordingly, the restatement adjustments resulted in no net income tax benefit or expense for any period presented, and the effective tax rate is unchanged.

3. Summary of Significant Accounting Policies

The significant accounting policies followed by the Company are summarized below:

Estimates - These 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 consolidated financial statements for any period necessarily involves the use of estimates and assumptions. Actual amounts may differ from these estimates. These 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, the estimated fair value of financial instruments, including warrants, and the accrual of state and local sales tax liabilities.

Cash and cash equivalents - Cash and cash equivalents consist of cash on hand and demand deposits. The demand deposits are highly liquid and readily convertible to known amounts of cash with insignificant risk of changes in value. They are considered to be cash equivalents as they have an original maturity of three months or less from the date of acquisition. The Company classifies all such highly liquid instruments that are not restricted as cash equivalents. Cash equivalents are stated at cost, which approximates fair value due to their short-term nature. For purposes of the statement of cash flows, the Company considers cash and cash equivalents to include cash on hand and demand deposits.

Accounts receivable - Accounts receivable are stated at the amount management expects to collect from outstanding balances. The Company maintains an allowance for credit losses to provide for the estimated amount of receivables that will not be fully collected. Management routinely assesses the financial strength of its customers and, consequently, believes accounts receivable are stated at the net realizable value and credit risk exposure is limited.

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.

Inventory - Inventory consists of purchased medical equipment and parts and is stated at the lower of first in, first out ("FIFO") method, or net realizable value less allowance for selling and distribution expenses. The Company analyzes its inventory levels and for adjustments to inventory that has, or is expected to, become obsolete.

Property, plant, and equipment (PPE) - PPE is initially recorded at cost, which includes all expenditures directly attributable to bringing the asset into working condition for its intended use. Subsequent to initial recognition, PPE is carried at cost less accumulated depreciation and any impairment losses. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, with no residual value for most assets. The estimated useful lives and residual values of assets are reviewed periodically and adjusted if necessary. Major improvements and enhancements that extend the useful life of PPE are capitalized, while routine repairs and maintenance are expensed as incurred. Upon disposal or retirement of an asset, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in the period of disposal.

Goodwill - Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company accounts for goodwill under ASC Topic 350, *Intangibles-Goodwill and Other*. The Company tests goodwill for impairment annually, or more frequently whenever events or circumstances indicate impairment may exist. Goodwill is stated at cost less impairment losses. The Company completes its goodwill impairment test annually in the fourth quarter. The Company performed a qualitative evaluation at the reporting unit level and determined there was no goodwill impairment as of December 31, 2025, and 2024.

Intangible assets - Intangible assets arising from the Company's acquisition are amortized on a straight-line basis over the estimated useful life of each asset. Customer relationships have a useful life of seven years. Patents and tradenames have a useful life of nineteen years.

Impairment of long-lived assets - The Company annually reviews long-lived assets for impairment whenever facts and circumstances indicate that the carrying amounts of the assets may not be recoverable. An impairment loss is recognized only if the carrying amount of the asset is not recoverable and exceeds its fair value. Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the asset's carrying value is not recoverable, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds its fair value. The Company determines fair value by using a combination of comparable market values and discounted cash flows, as appropriate.

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 sheets; lease expense for these leases 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.

Leases are classified as either operating or finance leases at the commencement date. The Company does not have any finance leases as of December 31, 2025. Operating lease ROU assets and liabilities are presented separately on the consolidated balance sheets.

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.

The Company's lease agreements do not contain variable lease payments; all lease payments are fixed and included in the measurement of lease liabilities.

Fair value of financial instruments - The carrying values of accounts payable, and other short-term obligations approximate their fair values, because of the short-term maturities of these instruments.

The Company utilizes the guidance of ASC Topic 820-10, *Fair Value Measurements* ("ASC 820-10"), which defines fair value, establishes a framework for measuring fair value and requires disclosures about fair value measurements. The framework that is set forth in this standard is applicable to the fair value measurements where it is permitted or required under other accounting pronouncements.

The ASC 820-10 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;
Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and
Level 3 – Unobservable inputs that are not corroborated by market data, therefore requiring the Company to develop its own assumptions.

Convertible promissory notes – The Company evaluates its convertible instruments to determine if those contracts, or embedded components of those contracts, qualify as derivative financial instruments to be separately accounted for in accordance with ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The accounting treatment of derivative financial instruments requires that the Company record embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. Conversion options are recorded as a discount to the host instrument and are amortized as amortization of debt discount on the consolidated statements of comprehensive loss over the life of the underlying instrument. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes because of events during the period, the contract is reclassified as of the date of the event that caused the reclassification.

Debt discount – The Company records a debt discount related to warrants issued with debt at fair value and recognizes the cost using the straight-line method, which approximates the effective interest method, over the term of the related debt as interest expense, which is reported in the *Other Income (Expense)* section in our consolidated statements of comprehensive income (loss). This debt discount is reported as a reduction of the related debt liability.

Contract liabilities – The Company offers a separately priced extended warranty. Because the extended multi-year warranty represents a separate performance obligation, revenue is deferred as a contract liability and recognized over the time that the Company satisfies its performance obligations, which is the warranty term.

Estimated Sales Tax Liability - The Company is evaluating a state sales tax liability analysis for states in which it has economic nexus, and collecting exemption documentation from its customers. The Company will be subject to sales tax liabilities plus interest and penalties relating to historical activity in certain states. The estimated liability for sales tax plus interest and penalties is recorded in *accrued expenses* in the consolidated balance sheets. The liability may change from the original estimate recorded due to the Company remitting cash to the proper state tax authorities for historical sales tax and interest, inquiries from collecting jurisdictions, and settlement of outstanding amounts through programs offered through those jurisdictions. Due to the estimates involved in the analysis, the Company expects that the estimated liability will change in the future, and may exceed the current estimate. The Company also may be subject to examination by the relevant state tax authorities, which could affect the amount the Company ultimately pays under the accrual. The Company recognized sales tax not collected from its customers along with penalties as *general and administrative expense* on the consolidated statements of comprehensive income (loss). The Company recognized interest expense on past due amounts not remitted as *interest expense* on the consolidated statements of comprehensive income (loss).

Segment reporting - The Company operates as a single reporting entity and has determined that it has one reportable segment. This conclusion is based on the fact that the Company's chief operating decision maker ("CODM"), who is the Chief Executive Officer ("CEO"), reviews the financial information and makes decisions about resource allocation and performance assessment on a consolidated basis. The Company's operations are managed and evaluated as a single business unit, and the nature of the products and services, production processes, and customer base are similar across the entire organization.

The Company is engaged in the business of designing and selling medical devices. The products and services offered by the Company are integrated and interrelated, and the Company does not have discrete financial information for different business lines that would qualify as separate reportable segments.

All significant accounting policies, including those related to revenue recognition, inventory valuation, property, plant, and equipment, and other key areas, are applied consistently across the entire organization.

Revenue recognition - The core principle of 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's revenue is primarily generated from the following activities:

System Sales, Consumables, Parts, and Accessories Sales - Systems, consumables, parts, and accessories sales include devices (new and refurbished), applicators, parts for the system, and accessories. 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. The Company provides a one-year standard warranty on its systems that are assurance-type warranties under ASC 606. Assurance-type warranties do not represent a separate performance obligation and thus the estimated costs associated with these warranties are recognized as a liability at the time the related revenue is recognized.

Extended Warranty - The Company allocates the transaction price to the extended warranty based on standalone selling price. Warranty revenue is recognized over the time that the Company satisfies its performance obligations, which is the warranty term.

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 rentals, repairs, and billed freight. The Company recognizes rental revenue ratably over the rental term, reflecting the period during which the customer has access to the system. 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.

The Company's products are sold with standard return rights that are customary in the industry. Historically, product returns have not been significant and have not had a material impact on the Company's financial statements. The Company monitors return activity on an ongoing basis and evaluates the need for a returns reserve at each reporting period. Based on historical experience and current trends, management believes that the risk of material returns is remote. As such, no material reserve for product returns has been recorded in the accompanying consolidated financial statements.

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs incurred have been recorded in *cost of revenues* totaling $590 thousand and $482 thousand for the years ended December 31, 2025, and 2024, respectively.

Research and development - Research and development costs are expensed as incurred. Research and development costs include costs of research, engineering, and technical activities to develop a new product, researching an expanded product use or making significant improvements to existing products, including the costs of clinical development.

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 option 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.

The Company issues new shares of common stock upon the exercise of stock options, warrants, and the vesting of restricted stock units.

Comprehensive income (loss) - Comprehensive income (loss) results from the translation of the Company's foreign entity's financial statements from their functional currency to U.S. dollars for consolidation in the accompanying consolidated financial statements.

Deferred offering costs - Deferred stock offering costs represent amounts paid for legal, consulting, and other offering expenses directly attributable to the offering of securities in conjunction with the recapitalization under the Merger Agreement (as defined in Note 21), and are deferred and charged against the gross proceeds of the offering. In the event of a significant delay or cancellation of a planned offering of securities, all the costs would be expensed. In June 2024, the Company terminated the Merger Agreement and the deferred offering costs of $0.5 million were expensed.

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 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 standard will have on the financial statement disclosures.

Recently adopted accounting pronouncements

ASU 2023-09, Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU primarily requires disaggregated annual information about a company's effective tax rate reconciliation and income taxes paid. The Company adopted this ASU prospectively beginning with 2025 and the additional disclosure is included in Note 18. Prior period disclosures have not been restated to conform to the current period presentation.

4. Allowance for Credit Losses

The rollforward of the allowance for credit losses is as follows:

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024
Allowance for credit losses, December 31	$ 1,147	$ 1,237
Provision for credit losses	202	171
Recoveries	-	2
Write-offs	(84)	(263)
Allowance for credit losses, December 31	$ 1,265	$ 1,147

5. Inventory

Inventory consisted of the following:

(in thousands)	December 31, 2025	December 31, 2024
Finished goods	$ 6,012	$ 755
Parts and accessories	135	3,763
Inventory reserve	(213)	$ (369)
Total Inventory	$ 5,934	$ 4,149

During the year ended December 31, 2025, the Company sold its PACE product line, as part of a strategic realignment to focus on core business offerings. As a result, management conducted a review of inventory associated with this product line and determined that a significant portion was no longer saleable or recoverable. Accordingly, the Company recorded a non-cash inventory write-off of $0.5 million, which is included in *cost of revenues* for the year ended December 31, 2025.

The write-off reflects management's estimate of the net realizable value of the affected inventory, in accordance with the Company's policy to state inventory at the lower of cost or net realizable value.

6. Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and impairment losses. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from 3 to 5 years.

The following table summarizes the components of property and equipment, net, and their estimated useful lives as of December 31, 2025 and 2024:

(in thousands)	December 31, 2025	December 31, 2024	Estimated Useful Life (Years)
Furniture and fixtures	$ 265	$ 90	3-5
Computer Equipment	22	-	3
Machinery and Equipment	1,020	642	3-5
Leasehold Improvements	1,023	31	Shorter of lease term or useful life (typically 5)
Property and equipment	2,330	763	
Less: Accumulated depreciation	(358)	(460)	
Property and equipment, net	$ 1,972	$ 303	

Depreciation expense related to property and equipment for the years ended December 31, 2025 and 2024 was approximately $392 thousand and $305 thousand, respectively. For the years ended December 31, 2025 and 2024, depreciation recognized within *cost of revenues* was $216 thousand and $220 thousand, respectively, and depreciation recognized within d*epreciation and amortization* was $176 thousand and $85 thousand, respectively, within the consolidated statements of income (loss).

Additions, Disposals, and Impairments

During 2025, the Company invested in new equipment to support increased production capacity and relocated its headquarters, resulting in additional machinery and equipment and leasehold improvements. There were no material disposals of property and equipment during the year. The Company recognized a $196 thousand loss on impairment of assets during the year ended December 31, 2025, related to the buyout of a finance lease agreement and subsequent impairment and disposal of the related assets. There were no impairments in 2024.

Operating lease assets are excluded from property and equipment, refer to Note 7.

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 received reimbursement payments from the lessor as a lease incentive. These payments, totaling $0.6 million, were intended to offset certain costs associated with leasehold improvements.

Lease expense - For the year ended December 31, 2025, the Company recognized lease expense of $123 thousand, related to this operating lease, which is included in *general and administrative expenses* in the consolidated statements of comprehensive income (loss).

As of December 31, 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
2026	$ 263
2027	272
2028	282
2029	292
2030	199
Thereafter	-
Total Lease Payments	1,308
Imputed interest	(297)
Present value of lease liabilities	$ 1,011

The weighted-average useful life of operating leases at December 31, 2025, is 4.67 years.

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

8. Intangible Assets

Carrying value of intangible assets consisted of the following:

(in thousands)	December 31, 2025 Gross	December 31, 2025 Accumulated Amortization	December 31, 2024 Gross	December 31, 2024 Accumulated Amortization	Weighted-Average Useful Life (in years)
Definite-lived Intangibles					
Customer relationships	$ 3,820	$ (2,945)	$ 3,820	$ (2,400)	0.5
Patents	2,312	(657)	2,312	(535)	2.2
Tradenames	693	(197)	693	(160)	7.5
Intangible Assets	$ 6,825	$ (3,799)	$ 6,825	$ (3,095)	10.2

Amortization expense for each of the years ended December 31, 2025, and 2024 totaled $704 thousand. Future amortization expense is expected to be the following (dollars in thousands):

Year ended December 31,	Amortization
2026	$ 704
2027	487
2028	158
2029	158
2030	158
Thereafter	$ 1,361

9. Long Term Debt, Revolving Credit Facility and Senior Secured Debt

The following table summarizes outstanding debt at December 31, 2025 and December 31, 2024:

(in thousands)	December 31, 2025 Principal	December 31, 2025 Debt Issuance Costs	December 31, 2025 Carrying Value	December 31, 2024 Principal	December 31, 2024 Debt Discount	December 31, 2024 Carrying Value
Secured term loan	$ 21,562	$ (257)	$ 21,305	$ -	$ -	$ -
Secured revolving credit facility	655	(68)	587	-	-	-
Senior secured debt	$ -	$ -	$ -	$ 26,898	$ (1,593)	$ 25,305

Revolving Credit Facility and Senior Secured Debt - On September 25, 2025, the Company entered into a new credit agreement (the "JPM Credit Agreement") with JPMorgan Chase Bank, N.A., as administrative agent, and a syndicate of lenders. The JPM Credit Agreement provides for a $23.0 million secured term loan (the "Term Loan") with term payments through September 25, 2029, and a $5.0 million secured revolving credit facility (the "Revolver") maturing September 25, 2027. Loans under the JPM Credit Agreement accrue interest at a rate per annum equal to, at the Company's option, either a term rate based on the secured overnight financing rate ("SOFR") plus a margin of 3.50%, or the CB Floating Rate ("CBFR") plus a margin of 2.50%. Interest is payable in arrears, either at the end of the applicable interest period for SOFR-based loans or quarterly for CBFR-based loans.

Debt issuance costs incurred in connection with obtaining new debt facilities are capitalized and amortized over the term of the related debt. For the term loan, these costs are presented as a direct reduction of the carrying amount of the debt. For the revolving credit facility, such costs are presented as an asset. Amortization of debt issuance costs is included in *interest expense* in the consolidated statements of comprehensive income (loss).

Principal payments on the term loan commenced on December 31, 2025, and will be made in quarterly installments of $1.4 million on the last day of each fiscal quarter. The Company may prepay outstanding loans at any time without premium or penalty, subject to customary breakage costs for SOFR-based borrowings.

Retirement of Senior Secured Debt - Concurrently, on September 25, 2025, in connection with the funding of the term loan and the initial draw of $0.7 million under the revolver, the Company paid all amounts due under and terminated in full all commitments under the Note and Warrant Purchase and Security Agreement, dated August 6, 2020, with NH Expansion Credit Fund Holdings LP and the related senior secured debt (collectively, the "Prior Debt"). The payoff and termination of the Prior Debt resulted in the release of all associated liens and security interests.

The full repayment of the Prior Debt was accounted for as a debt extinguishment under ASC 470-50. The Company recognized a $0.5 million loss on extinguishment of debt, which included the write-off of unamortized debt issuance costs and debt discounts.

Debt Covenants and Restrictions - The JPM Credit Agreement contains customary covenants, including requirements to maintain certain financial ratios and restrictions on additional indebtedness, asset sales, and dividend payments.

As of December 31, 2025, the Company was in compliance with all covenants under the JPM Credit Agreement.

Collateral and Security - The Company's obligations under the JPM Credit Agreement are secured by a first-priority lien on substantially all of the Company's tangible and intangible assets, including the Company's equity interests in subsidiaries.

Maturity Analysis - Future principal payments on the term loan and revolver are due as follows:

(in thousands)	Principal Payments
2026	$ 5,750
2027 (including the revolver)	6,405
2028	5,750
2029	4,312
Total Principal Payments	22,217
Debt Issuance Costs	(325)
Total	21,892
Less current maturities	(5,750)
Long term debt, net of current maturities and debt issuance costs	$ 16,142

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

	Year Ended	
(in millions)	December 31, 2025	December 31, 2024
Amortization of debt issuance costs and debt discount, included in interest expense	$ 1.6	$ 2.1
Interest expense	$ 5.5	$ 8.1

10. Accounts Payable and Accrued Expenses

Accounts payable consisted of the following:

(in thousands)	December 31, 2025	December 31, 2024
Trade Accounts Payable	3,219	3,684
Other	32	44
Total Accounts Payable	$ 3,251	$ 3,728

Accrued expenses consisted of the following:

(in thousands)	December 31, 2025	December 31, 2024 (As Restated)
Registration penalties	$ 1,583	$ 1,583
State & Local Sales Tax	3,885	2,512
State & Local Sales Tax Penalties	571	378
State & Local Sales Tax Interest	464	188
Board of directors fees	172	249
Employee compensation	1,220	2,232
Other	487	614
Total Accrued Expenses	$ 8,382	$ 7,756

11. Fair Value Measurements

The Company uses various inputs to measure the outstanding warrants and certain embedded conversion features associated with convertible debt on a recurring basis to determine the fair value of the liabilities. As of December 31, 2025, the fair value of the warrant liability was not significant. The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy:

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

There were no transfers between Level 1, 2, or 3, during the years ended December 31, 2025, and 2024. Both observable and unobservable inputs were used to determine fair value of the positions that the Company classified within the Level 3 category. Unrealized gains and losses associated with the 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 December 31, 2025, and 2024, were valued using the Black-Scholes valuation model.

The Company's initial valuation of warrant liability from the June 2024 financing was valued using a probability weighted expected value considering the proposed reverse stock split of the Company's common stock (the "Reverse Stock Split") that would effectuate the exchange of Notes and Common Stock Purchase Warrants for shares of the Company's common stock (the "Note and Warrant Exchange"), and the previous Black-Scholes valuation model, with significant value stemming from the Note and Warrant Exchange. Significant inputs under the Note and Warrant Exchange included the

expected exchange ratio of 0.90 for $15.00 warrants and 0.85 for $25.13 warrants, the value of the Company's common stock, the expected timing of the Reverse Stock Split effectuating, and the probability of the Note and Warrant Exchange occurring (90% probability).

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

	December 31, 2025	December 31, 2024
Weighted average expected life in years	0.68	0.85
Weighted average volatility	58%	91%
Value of underlying shares	$29.84	$22.76
Weighted average risk free interest rate	3.49%	4.10%
Expected dividend yield	0%	0%

A summary of the Level 3 warrant activity is as follows:

(in thousands, except per share data)	Warrants Outstanding	Fair Value per Share	Warrant Liability Fair Value
Balance December 31, 2023	3,594	$ 4.02	$ 14,447
Issuance of warrants classified as liabilities	781	4.55	3,557
Exercised	(107)	5.73	(613)
Converted to equity	(3,883)	10.50	(40,772)
Forfeited or expired	5	-	-
Change in fair value	-	-	31,488
Balance December 31, 2024	390	$ 20.79	$ 8,107
Expired	(388)		
Change in fair value	-		(8,107)
Balance December 31, 2025	2	$ 0.26	$ -

A summary of the warrant activity is as follows:

(in thousands, except per share data)	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
Warrants Outstanding at December 31, 2023	3,594	$ 22.50	4.01
Issuance of warrants classified as liabilities	781	20.06	
Exercised	(107)	29.45	
Converted to equity	(3,883)	20.06	
Forfeited or expired	5	-	
Change in fair value	-		
Warrants Outstanding at December 31, 2024	390	4.05	0.86
Expired	(388)		
Change in fair value	-		
Warrants Outstanding at December 31, 2025	2	74.25	0.68

Embedded Conversion Option

Certain convertible notes include a conversion option that meets the definition of a derivative liability and, accordingly, is required to be bifurcated. The fair value for the conversion option liability of the June 2024 transaction was valued using a

probability weighted expected value considering the proposed Reverse Stock Split of the Company's common stock that would effectuate the Note and Warrant Exchange, and the previous Black-Scholes valuation model, with significant value stemming from the Note and Warrant Exchange. Significant inputs under the Note and Warrant Exchange included the value of the Company's common stock, the expected timing of the Reverse Stock Split effectuating, and the probability of the Note and Warrant Exchange occurring (90% probability).

In October 2024, the Company exchanged all outstanding convertible notes for Common Stock as part of the Note and Warrant Exchange, see Note 13.

A summary of the conversion option liability activity is as follows:

(in thousands)	Conversion Liability
Balance December 31, 2023	$ 93
Issuance of Convertible Notes	8
Settlement of convertible notes	(26)
Change in fair value	(75)
Balance December 31, 2024	$ -

12. Contract Liabilities

During the years ended December 31, 2025, and 2024, the Company recognized revenue related to these contract liabilities of $172 thousand and $95 thousand, respectively, that were included in the beginning contract liability balances for each of those periods.

The following table summarizes the changes in contract liabilities:

	Year Ended December 31,	
(in thousands)	2025	2024
Beginning balance	$ 493	$ 439
New service agreements	768	149
Revenue recognized	(172)	(95)
Total Contract Liabilities	$ 1,089	$ 493

As of December 31, 2025, the Company expects to recognize revenue from its contract liabilities as follows:

(in thousands)	Amount
2026	$ 388
2027	495
2028 and thereafter	206
Total Contract Liabilities	$ 1,089

13. 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 years ended December 31, 2025 and 2024 totaled $0 and $5.0 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 94,130 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.

14. Common Stock

In December 2022, the Company's stockholders approved an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 800,000,000 to 2,500,000,000. In January 2023, the Company filed the amendment to the Articles of Incorporation with the state of Nevada to affect the increase in authorized shares.

Private Investment in Public Equity (PIPE) Transaction

On October 16, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with the purchasers (the "Purchasers"), for the private placement (the "Private Placement") of approximately 1.3 million shares (the "Shares") of common stock at a purchase price of $8.25 per share, in each case, after adjustment to reflect the Reverse Stock Split. The Private Placement closed on October 18, 2024, and aggregate gross proceeds were approximately $10.3 million, before deducting $0.1 million offering expenses.

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

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

15. Revenue

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

(in thousands)	Year ended December 31, 2025	Year ended December 31, 2024
Consumables, parts, and accessories revenue	$ 25,804	$ 21,116
System revenue	17,849	11,072
Extended warranty	172	95
License fees	20	45
Other	206	306
Total Revenue	$ 44,051	$ 32,634

16. 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. On August 19, 2025, at our annual meeting of stockholders, an amendment to the 2024 Plan was approved, authorizing an additional 500,000 shares of common stock authorized for issuance under the 2024 Plan. 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 fiscal year ended December 31, 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 fiscal year ended December 31, 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 and 5,000 shares under criterion (e) were forfeited due to the milestone deadline not being achieved. As a result, the maximum number of shares eligible to vest under these awards was reduced to 55,000 shares as of December 31, 2025.

As of December 31, 2025, the Company concluded that the performance conditions related to revenue and adjusted EBITDA were not probable of achievement, and accordingly, no compensation expense was recognized for those awards. The debt refinancing condition, the listing on Nasdaq and half of the various operations related milestones were achieved during the fiscal year ended December 31, 2025, and the related compensation expense was recognized in the year.

The market condition has not been met as of December 31, 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 fiscal years ended December 31, 2025 and 2024. Total unrecognized compensation cost related to equity awards as of December 31, 2025 was $10.3 million and is expected to be recognized over a weighted average period of 2.25 years. Total unrecognized compensation cost related to equity awards as of December 31, 2024 was $8.3 million and was expected to be recognized over a period of 3 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. The Company recognizes compensation expense on a straight-line basis over the requisite service period, net of actual forfeitures.

	Year ended December, 31	
(in thousands)	2025	2024
Cost of revenues	$ 52	$ -
General and administrative	3,929	1,514
Selling and marketing	826	-
Research and development	43	-
Total expense	$ 4,850	$ 1,514

The following table presents a summary of stock option activity:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding	43	$ 51.55	3.4	$ -
Granted	1,119	-	9.8	9,253
Exercised	-	-	–	-
Forfeited	(25)	-	–	-
Outstanding, December 31, 2024	1,137	$ 15.97	9.5	$ 9,305
Exercisable, December 31, 2024	117	$ 28.71	6.8	$ 641
Granted	541	31.07	7.7	617
Exercised	(38)	14.67	-	575
Forfeited	(268)	18.42	-	-
Outstanding, December 31, 2025	1,372	$ 21.46	8.4	$ 13,351
Exercisable, December 31, 2025	493	$ 20.08	7.9	$ 5,581

Valuation Information for Stock-Based Compensation

The fair value of each stock option award during the fiscal year ended December 31, 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 years ended December 31, 2025 and December 31, 2024 are summarized in the table below:

	Year Ended December 31,	
	2025	2024
Fair value at grant date	31.13	14.54
Expected volatility	62.9%	62.8%
Risk-free interest rate	4.0%	4.1%
Expected holding period, in years	5.2 years	6.1 years
Dividend yield	-	-

17. 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)	December 31, 2025	December 31, 2024 (As Restated)
Numerator:		
Basic net income (loss) available to stockholders	$ 11,813	$ (33,083)
Change in fair value of warrants	(8,107)	-
Diluted net income (loss) available to stockholders	3,706	(33,083)
Denominator:		
Weighted average common shares outstanding - Basic	8,564	4,463
Dilutive effect of stock options	298	-
Dilutive effect of warrants	221	-
Weighted average common shares outstanding - Diluted	9,083	4,463
Net income (loss) per share:		
Basic	$ 1.38	$ (7.41)
Diluted	$ 0.41	$ (7.41)

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding. To the extent that securities are “anti-dilutive,” they are excluded from the calculation of diluted net loss per share. As a result of the net loss

for the year ended December 31, 2024, all potentially dilutive shares in the period were anti-dilutive and therefore excluded from the computation of diluted net loss per share. Anti-dilutive equity securities consist of the following:

(in thousands)	December 31, 2025	December 31, 2024
Common stock options	$ 340	$ 1,137
Restricted stock units- unvested	-	5
Common stock purchase warrants	2	390
	$ 342	$ 1,532

18. Income Taxes

The Company files income tax returns in the United States federal jurisdiction and various state and foreign jurisdictions. The Company is subject to United States federal and state income tax examinations by tax authorities for any years that have net operating losses open until the net operating losses are used.

The components of the net income (loss) before income taxes are as follows:

	Year ended December 31,	
(In thousands)	2025	2024 (As restated)
Domestic	$ 11,899	$ (33,030)
Foreign	-	(26)
Net income (loss) before income taxes	$ 11,899	$ (33,056)

In accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), the Company accounts for income taxes utilizing the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets, including loss carryforwards, when it is more likely than not that some portion or all a deferred tax asset will not be realized.

The income tax provision (benefit) from continuing operations consists of the following:

(In thousands)	December 31, 2025	December 31, 2024 (As restated)
Current:		
Federal	$ 40	$ -
State	46	27
Foreign	-	-
Current Tax Provision	$ 86	$ 27
Deferred:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Deferred Tax Provision	$ -	$ -

As of December 31, 2025, and 2024, the Company did not have any undistributed earnings of our foreign subsidiaries. As a result, no additional income or withholding taxes have been provided for. The Company does not anticipate any impacts of the global intangible low taxed income ("GILTI") and base erosion anti-abuse tax ("BEAT") and as such, the Company has not recorded any impact associated with either GILTI or BEAT.

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows:

(In thousands)	For the year ended December 31, 2025	
	Amount	Percent
Tax at United States statutory rate	$ 2,499	21.0 %
State and local income taxes[1]	36	0.3
Changes in valuation allowance	(10,888)	(91.5)
Nontaxable and nondeductible items:		
Stock-based compensation	722	6.9
Warrant revaluation	(1,702)	(14.3)
Net operating losses limited under section 382	9,282	77.9
Other	137	0.4
Effective Tax Rate	$ 86	0.7 %

[1] The states and local jurisdictions that contribute to the majority (greater than 50%) of the tax effect in this category include Texas.

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for the year prior to adoption of ASU 2023-09 is as follows:

(In thousands)	For the year ended December 31, 2024 (As restated)
Tax benefit at statutory rate	$ (6,942)
Increase (reduction) in income taxes resulting from:	
State income tax benefits, net of federal benefit	10
Non-deductible gain on warrant adjustment valuation	6,596
Change in valuation allowance	(1,177)
Warrant revaluation	1,264
Other	276
Effective Tax Rate	$ 27

The tax effects of temporary differences that give rise to the deferred tax assets are as follows:

(In thousands)	December 31, 2025	December 31, 2024 (As restated)
Deferred Tax Assets		
Net operating loss carryforwards	$ 28,798	$ 41,276
Net operating loss carryforwards - foreign	19	19
Excess of tax basis over book value of property and equipment	-	53
Excess of tax basis over book value of intangible assets	775	961
Lease liability	219	110
Stock-based compensation	1,794	1,668
Accrued employee compensation	167	212
Capitalized research and development	4	340
Other	12	-
Sales tax accrual	942	600
Net change in reserve accounts	771	819
Gross deferred tax asset	33,501	46,058
Valuation Allowance	(32,984)	(45,943)
Net Deferred Tax Asset	517	115
Deferred Tax Liabilities		
Accrued miscellaneous	(2)	-
Right-of-use asset	(84)	(95)
Depreciation	(431)	-
Reserve for credit losses	-	(20)
Gross deferred tax liability	(517)	(115)
Total	$ -	$ -

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. In assessing the realization of deferred tax assets, management considers, whether it is “more likely than not”, that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible.

ASC 740 requires that a valuation allowance be established when it is "more likely than not" that all, or a portion of, deferred tax assets will not be realized. A review of all available positive and negative evidence needs to be considered, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. After consideration of all the information available, management believes that uncertainty exists with respect to future realization of its deferred tax assets and has, therefore, established a full valuation allowance as of December 31, 2025, and 2024.

Federal and state tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 ("Section 382"). The Company has completed a formal Section 382 analysis and determined a change in control occurred on October 18, 2024. The Company is subject to a federal Section 382 annual limitation of $4 million annually for the five years after the change in control, and a $1.3 million annual limitation thereafter. Deferred tax assets totaling $44.2 million are expected to expire unutilized and have been adjusted.

The Federal net operating loss carryforwards of approximately $27.6 million incurred from the years ended December 31, 2005, through December 31, 2017, will begin to expire in 2026. The Federal net operating loss carryforward for the years ended December 31, 2018, through 2025 of approximately $94.8 million will not expire. The state net operating loss carryforwards of approximately $46.2 million from years ending December 31, 2005, through December 31, 2025, will expire at various dates through 2043.

A provision of ASC 740 specifies that companies are to account for uncertainties in income tax reporting, and prescribes a methodology for recognizing, reversing, and measuring the tax benefits of a tax position taken, or expected to be taken, in a tax return. ASC 740 requires the evaluation of tax positions taken or expected to be taken while preparing the Company's tax returns to determine whether the tax positions would "more-likely-than-not" be sustained if challenged by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax benefit or expense in the current year. Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements as of December 31, 2025, and 2024. The Company does not expect any significant changes in the unrecognized tax benefits within twelve months of the reporting date.

The Company will recognize in income tax expense, interest and penalties related to income tax matters. For the years ended December 31, 2025, and 2024, the Company did not have any amounts recorded for interest and penalties.

The amount of cash income taxes paid by the Company were as follows:

(In thousands)	For the year ended December 31, 2025
Federal	$ -
State and local	
Texas	25
All other states	2
Foreign	-
Total	$ 27

The total cash income taxes paid by the Company during the year ended December 31, 2024 was $4 thousand.

19. Concentration of Credit Risk and Limited Suppliers

Major customers are those whose accounts receivable or sales individually comprise ten percent or more of the Company's total trade receivables or total sales, respectively. As of December 31, 2025, the Company had the following concentrations

of accounts receivable attributable to individual customers. There were no sales concentrations as of December 31, 2025, and there were no sales or trade receivable concentrations as of December 31, 2024.

(in thousands)	December 31, 2025	% of Total AR
Customer:		
Customer A	$ 829	12%

As of December 31, 2025, one customer accounted for more than 10% of total accounts receivable. The Company does not believe that the loss of this customer would have a material adverse effect on its financial position, results of operations, or cash flows.

Cash and Cash Equivalents

Cash equivalents are financial instruments that potentially subject the Company to concentration of credit risk. As of December 31, 2025, the Company's cash equivalent securities were largely comprised of money market funds. The Company’s cash accounts are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000 per financial institution in the United States.

Limited Suppliers

The Company currently purchases most of its product component materials from single suppliers and all of its finished product is assembled by a single supplier. The loss of any of these suppliers could result in a disruption in our production. The percentage of purchases from major vendors of the Company that represented ten percent or more of total purchases were as follows:

	Year ended December 31,	
	2025	2024
Purchases:		
Vendor A	26%	26%

20. 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 fiscal year ended December 31, 2024. The Company granted the Licensee an exclusive license to the patents and an option to acquire the patents 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.

On July 23, 2025, the Licensee exercised the acquisition option. In connection with such exercise, the Licensee and the Company executed a patent purchase agreement, and the Licensee made a $5.0 million cash payment to Sanuwave, Inc. on August 21, 2025. At the time of the Patent License and through the Licensee's exercise of the acquisition option, the Company did not have any amounts capitalized related to the underlying portfolio of patents, nor was any write-down of assets recorded upon executing the Patent License or acquisition option. Accordingly, the Company recognized a $5.0 million gain on sale of patents within o*ther income (expense)* on the consolidated statements of comprehensive income (loss) for the fiscal year ended December 31, 2025. The Company does not have any ongoing obligations associated with the patent license. Additional proceeds may be provided to the Company under certain conditions of the agreement with the Licensee.

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.

21. 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 Companies expenses legal fees in the period in which they are incurred.

In August 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 whole owned subsidiary of SEPA. Pursuant to the terms of the Merger Agreement, a business combination between the Company and SEPA was to be effected. In February 2024, the Company entered into a termination agreement with an advisor to agree on termination fees owed with respect to a previous engagement agreement. The Company agreed to a contingent payment of $0.7 million upon the closure of the Merger. Upon the Company's termination of the Merger Agreement in June 2024, the related contingent consideration liability was derecognized.

Acquisition Dispute

In May 2022, the Company received notification alleging that it is not in compliance with the license agreement with Celularity entered in connection with the acquisition of the UltraMIST assets. The Company settled this dispute in June 2024 for a cash payment of $2.2 million, which resulted in the removal of $4.0 million in convertible promissory note payable, $2.4 million in accrued interest, $0.9 million of accrued expenses, $0.5 million of other liabilities, and $0.4 million in accounts receivable, which resulted in the recognition of a gain on extinguishment of debt of $5.3 million.

22. Segment Information

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

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

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, Chief Executive Officer, is the CODM.

The following table sets forth our consolidated statement of operations used by the CODM:

	For the Years Ended December 31,	
(in thousands)	2025	2024 (As Restated)
Revenue	$ 44,051	$ 32,634
Cost of revenue	10,082	8,084
Gross margin	33,969	24,550
Operating expenses:		
General and administrative	19,372	12,917
Selling and marketing	7,419	6,323
Research and development	1,353	673
Depreciation and amortization	880	789
Operating Income	4,945	3,848
Total Other Income (Expense)	6,954	(36,904)
Income tax expense	86	27
Net Income (Loss)	$ 11,813	$ (33,083)

23. Going Concern

The accompanying consolidated 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. In prior periods, the Company experienced recurring net losses, accumulated deficits, negative working capital, and significant debt maturities, which raised substantial doubt about its ability to continue as a going concern.

During the third quarter of fiscal year 2025, management executed a comprehensive debt refinancing with a new lender, which extended the maturity of the Company's principal debt obligations from the secured term loan and provided the option for additional liquidity to support ongoing operations through a secured revolving credit facility. In addition, the Company achieved positive operating income for the fiscal years ended December 31, 2025, and 2024, reflecting the impact of strategic initiatives focused on revenue growth and operational efficiency.

As a result of these actions, management has evaluated the Company's financial condition and cash flow requirements for the twelve months following the issuance of these consolidated financial statements. Based on the debt refinancing, achievement of operating income, and expected cash inflows from forecasted operations for at least the next 12 months, management believes the Company has sufficient resources to meet its obligations as they become due and to continue its operations for the foreseeable future. Accordingly, when considering all conditions and factors, management concluded that the substantial doubt about the Company's ability to continue as a going concern was alleviated as of the third quarter of fiscal year 2025.

Management will continue to monitor the Company’s financial position, operating results, and compliance with debt covenants.

24. Restatement of 2025 and 2024 Quarterly Financial Information (Unaudited):

In connection with the restatement described herein, the Company's previously issued unaudited condensed consolidated financial statements included in the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2025, June 30, 2025, and September 30, 2025, and for the quarters ended March 31,2024, June 30, 2024, and September 30, 2024, should no longer be relied upon. The following tables present the effects of the restatement on the Company's previously reported: unaudited condensed consolidated statements of comprehensive income (loss) for the three months ended March 31, 2025 and 2024, the three and six months ended June 30, 2025 and 2024, the three and nine months ended September 30, 2025 and 2024; and the unaudited condensed consolidated statements of cash flows for the three months ended March 31, 2025 and 2024, the six months ended June 30, 2025 and 2024, and the nine months ended September 30, 2025 and 2024. The restatement impacts net income (loss) and accumulated other comprehensive loss in the Unaudited Condensed Consolidated Statements of Changes in Stockholders’ Equity (Deficit) in the periods presented.

In addition to the errors noted in Note 2 related to sales tax liabilities, the Company identified that revenue was overstated and contract liabilities were understated for the three months ended March 31, 2025, the three and six months ended June 30, 2025 and three and nine months ended September 30, 2025. The errors related to the Company's accounting for extended warranty contracts sold at a discount in conjunction with its products. When extended warranties were sold at a discounted price, the Company did not allocate the discount proportionally across all performance obligations in the contract in accordance with ASC 606, *Revenue from Contracts with Customers*.

Specifically, ASC 606 requires that a discount present in a contract be allocated proportionally across all performance obligations based on their relative standalone selling prices, unless specific criteria are met to allocate the discount entirely to one or more performance obligations. The Company incorrectly absorbed the entire discount within the extended warranty performance obligation rather than allocating a proportionate share of the discount to the other performance obligations in the contract. This caused the transaction price allocated to the extended warranty to be understated and the transaction price allocated to the other performance obligations to be overstated, resulting in revenue being recognized on the other performance obligations in excess of the amounts that should have been allocated to them. Consequently, revenue was overstated and contract liabilities associated with the extended warranty was understated for the three months ended March 31, 2025, the three and six months ended June 30, 2025 and three and nine months ended September 30, 2025

Restated 2025 Quarterly Financial Information (Unaudited) - Reconciliation Tables

The following tables presents the impact of the restatement on the Company’s previously issued Unaudited Condensed Consolidated Balance Sheets as of March 31, 2025, June 30, 2025, and September 30, 2025.

(in thousands)		As of March 31, 2025		
Unaudited Condensed Consolidated Balance Sheet	Notes	As Previously Reported	Adjustment	As Restated
Accrued expenses	(i)	$ 3,581	$ 3,511	$ 7,092
Current portion of contract liabilities	(ii)	193	1	194
Total Current Liabilities		47,268	3,512	50,780
Contract liabilities, less current portion	(iii)	311	8	319
Total Liabilities		48,147	3,520	51,667
Accumulated Deficit		(257,097)	(3,520)	(260,617)
Total Stockholders' Deficit		$ (17,292)	$ (3,520)	$ (20,812)

		As of June 30, 2025		
Unaudited Condensed Consolidated Balance Sheet	Notes	As Previously Reported	Adjustment	As Restated
Accrued expenses	(i)	$ 3,289	$ 3,905	$ 7,194
Current portion of contract liabilities	(ii)	221	10	231
Total Current Liabilities		46,501	3,915	50,416
Contract liabilities, less current portion	(iii)	301	109	410
Total Liabilities		47,821	4,024	51,845
Accumulated Deficit		(256,042)	(4,024)	(260,066)
Total Stockholders' Deficit		$ (14,775)	$ (4,024)	$ (18,799)

		As of September 30, 2025		
Unaudited Condensed Consolidated Balance Sheet	Notes	As Previously Reported	Adjustment	As Restated
Accrued expenses	(i)	$ 3,586	$ 4,361	$ 7,947
Current portion of contract liabilities	(ii)	252	47	299
Total Current Liabilities		19,577	4,408	23,985
Contract liabilities, less current portion	(iii)	322	253	575
Total Liabilities		38,530	4,661	43,191
Accumulated Deficit		(245,717)	(4,661)	(250,378)
Total Stockholders' Deficit		$ (2,931)	$ (4,661)	$ (7,592)

A description of the restatement adjustments in the consolidated balance sheets is as follows:

(i) The $3.5 million, $3.9 million, and $4.4 million increases in accrued expenses as of March 31, 2025, June 30, 2025, and September 30, 2025, respectively, are related to the accrued sales tax, and the related interest and penalties on outstanding sales tax balances through each reporting date.

(ii) The $1 thousand, $10 thousand, and $47 thousand increases in the current portion of contract liabilities as of March 31, 2025, June 30, 2025, and September 30, 2025, respectively, are related to the adjustment to contract liabilities balances at each reporting date.

(iii) The $8 thousand, $109 thousand, and $253 thousand increases in the non-current portion of contract liabilities as of March 31, 2025, June 30, 2025, and September 30, 2025, respectively, are related to the adjustments to contract liabilities associated with extended warranties.

The following table presents the impact of the restatement on the Company's previously issued Unaudited Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2025, the three and six months ended June 30, 2025, and the three and nine months ended September 30, 2025.

(in thousands, except per share data)		For the three months ended March 31, 2025		
Unaudited Condensed Consolidated Statement of Comprehensive Loss	Notes	As Previously Reported	Adjustment	As Restated
Revenue	(i)	$ 9,342	$ (9)	$ 9,333
Gross Margin		7,384	(9)	7,375
General and administrative	(ii)	4,467	376	4,843
Total Operating Expenses		6,398	376	6,774
Operating Income (Loss)		986	(385)	601
Interest expense	(iii)	(1,852)	(57)	(1,909)
Total Other Expense		(6,662)	(57)	(6,719)
Net Loss		(5,676)	(442)	(6,118)
Total Comprehensive Loss		(5,676)	(442)	(6,118)
Net Loss per share: basic and diluted		$ (0.66)	$ (0.05)	$ (0.72)

(in thousands, except per share data)		For the three months ended June 30, 2025			For the six months ended June 30, 2025		
Unaudited Condensed Consolidated Statement of Comprehensive Income (Loss)	Notes	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
Revenue	(i)	$ 10,164	$ (110)	$ 10,054	$ 19,506	$ (119)	$ 19,387
Gross Margin		7,958	(110)	7,848	15,342	(119)	15,223
General and administrative	(ii)	4,039	329	4,368	8,506	705	9,211
Total Operating Expenses		6,081	329	6,410	12,479	705	13,184
Operating Income		1,877	(439)	1,438	2,863	(824)	2,039
Interest expense	(iii)	(1,874)	(65)	(1,939)	(3,726)	(122)	(3,848)
Total Other Expense		(822)	(65)	(887)	(7,484)	(122)	(7,606)
Net Income (Loss)		1,055	(504)	551	(4,621)	(946)	(5,567)
Total Comprehensive Income (Loss)		1,055	(504)	551	(4,621)	(946)	(5,567)
Net Income (Loss) per share: basic		$ 0.12	$ (0.06)	$ 0.06	$ (0.54)	$ (0.11)	$ (0.65)
Net Income (Loss) per share: diluted		$ 0.01	$ (0.05)	$ (0.04)	$ (0.54)	$ (0.11)	$ (0.65)

(in thousands, except per share data)		For the three months ended September 30, 2025			For the nine months ended September 30, 2025		
Unaudited Condensed Consolidated Statement of Comprehensive Income (Loss)	Notes	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
Revenue	(i)	$ 11,451	$ (181)	$ 11,270	$ 30,957	$ (300)	$ 30,657
Gross Margin		8,925	(181)	8,744	24,267	(300)	23,967
General and administrative	(ii)	4,810	383	5,193	13,316	1,088	14,404
Total Operating Expenses		7,458	383	7,841	19,937	1,088	21,025
Operating Income (Loss)		1,467	(564)	903	4,330	(1,388)	2,942
Interest expense	(iii)	(1,722)	(73)	(1,795)	(5,448)	(195)	(5,643)
Total Other Expense		8,858	(73)	8,785	1,374	(195)	1,179
Net Income (Loss)		10,325	(637)	9,688	5,704	(1,583)	4,121
Total Comprehensive Income (Loss)		10,325	(637)	9,688	5,704	(1,583)	4,121
Net Income (Loss) per share: basic		$ 1.20	$ (0.07)	$ 1.13	$ 0.67	$ (0.18)	$ 0.48
Net Income (Loss) per share: diluted		$ 0.46	$ (0.07)	$ 0.39	$ 0.38	$ (0.17)	$ 0.21

A description of the restatement adjustments in the consolidated statements of comprehensive income (loss) is as follows:

(i) The $9 thousand decrease in revenue for the three months ended March 31, 2025, the $110 thousand decrease for the three months ended June 30, 2025, the $119 thousand decrease for the six months ended June 30, 2025, the $181 thousand decrease for the three months ended September 30, 2025, and the $300 thousand decrease for the nine months ended September 30, 2025, are related to the adjustment to revenue associated with extended warranties.

(ii) The $0.4 million increase in general and administrative expenses for the three months ended March 31, 2025, the $0.3 million increase for the three months ended June 30, 2025, the $0.7 million increase for the six months ended June 30, 2025, the $0.4 million increase for the three months ended September 30, 2025, and the $1.1 million increase for the nine months ended September 30, 2025, are related to the adjustment for estimated state and local sales tax expense and for the related penalties on outstanding sales tax balances.

(iii) The $57 thousand increase in interest expense for the three months ended March 31, 2025, the $65 thousand increase for the three months ended June 30, 2025, the $122 thousand increase for the six months ended June 30, 2025, the $73 thousand increase for the three months ended September 30, 2025, and the $195 thousand increase for the nine months ended September 30, 2025, are related to the adjustment for estimated interest on outstanding state and local sales tax balances.

The tables below present the previously reported and restated cash flow data for the three months ended March 31, 2025, the six months ended June 30, 2025, and the nine months ended September 30, 2025. The restated amounts reflect the correction of the error described above.

(in thousands)		For the three months ended March 31, 2025		
Unaudited Condensed Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Loss		$ (5,676)	$ (442)	$ (6,118)
Accrued expenses and Contract liabilities	(i)	(774)	442	(332)
Net Cash Used in Operating Activities		$ (1,517)	$ -	$ (1,517)

		For the six months ended June 30, 2025		
Unaudited Condensed Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Loss		$ (4,621)	$ (946)	$ (5,567)
Accrued expenses and Contract liabilities	(i)	(746)	946	200
Net Cash Used in Operating Activities		$ (524)	$ -	$ (524)

		For the nine months ended September 30, 2025		
Unaudited Condensed Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Income (Loss)		$ 5,704	$ (1,583)	$ 4,121
Accrued expenses and Contract liabilities	(i)	(294)	1,583	1,289
Net Cash Provided by Operating Activities		$ 557	$ -	$ 557

A description of the restatement adjustments in the consolidated statements of cash flows is as follows:

(i) The $0.4 million, $0.9 million, and $1.6 million increases in accrued expenses for the three months ended March 31, 2025, the six months ended June 30, 2025, and the nine months ended September 30, 2025, respectively, are related to accrued sales tax, and the related interest and penalties on outstanding sales tax balances, and the adjustments to contract liabilities associated with extended warranties.

Restated 2024 Quarterly Financial Information (Unaudited) - Reconciliation Tables

The following table presents the impact of the restatement on the Company's previously issued Unaudited Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2024, the three and six months ended June 30, 2024, and the three and nine months ended September 30, 2024.

(in thousands, except per share data)		For the three months ended March 31, 2024		
Unaudited Condensed Consolidated Statement of Comprehensive Loss	Notes	As Previously Reported	Adjustment	As Restated
General and administrative	(i)	$ 3,675	$ 244	$ 3,919
Total Operating Expenses		5,252	244	5,496
Operating Loss		(1,050)	(244)	(1,294)
Interest expense	(ii)	(3,237)	(26)	(3,263)
Total Other Expense		(3,478)	(26)	(3,504)
Net Loss		(4,528)	(270)	(4,798)
Total Comprehensive Loss		(4,417)	(270)	(4,687)
Net Loss per share: basic and diluted		$ -	$ -	$ -

		For the three months ended June 30, 2024			For the six months ended June 30, 2024		
Unaudited Condensed Consolidated Statement of Comprehensive Income (Loss)	Notes	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
General and administrative	(i)	$ 1,839	$ 345	$ 2,184	$ 5,514	$ 589	$ 6,103
Total Operating Expenses		3,248	345	3,593	8,500	589	9,089
Operating Income (Loss)		1,992	(345)	1,647	942	(589)	353
Interest expense	(ii)	(3,396)	(30)	(3,426)	(6,633)	(56)	(6,689)
Total Other Expense		4,569	(30)	4,539	1,091	(56)	1,035
Net Income (Loss)		6,561	(375)	6,186	2,033	(645)	1,388
Total Comprehensive Income (Loss)		6,571	(375)	6,196	2,154	(645)	1,509
Net Income per share: basic		$ 0.01	$ -	$ 0.01	$ -	$ -	$ -
Net Income per share: diluted		$ -	$ -	$ -	$ -	$ -	$ -

		For the three months ended September 30, 2024			For the nine months ended September 30, 2024		
Unaudited Condensed Consolidated Statement of Comprehensive Loss	Notes	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
General and administrative	(i)	$ 2,545	$ 470	$ 3,015	$ 8,059	$ 1,059	$ 9,118
Total Operating Expenses		5,114	470	5,584	13,614	1,059	14,673
Operating Income (Loss)		1,953	(470)	1,483	2,895	(1,059)	1,836
Interest expense	(ii)	(3,315)	(38)	(3,353)	(9,948)	(94)	(10,042)
Total Other Expense		(22,610)	(38)	(22,648)	(21,519)	(94)	(21,613)
Net Loss		(20,657)	(508)	(21,165)	(18,624)	(1,153)	(19,777)
Total Comprehensive Loss		(20,657)	(508)	(21,165)	(18,503)	(1,153)	(19,656)
Net Loss per share: basic and diluted		$ (6.49)	$ (0.16)	$ (6.65)	$ (5.92)	$ (0.37)	$ (6.29)

A Description of the restatement adjustments in the consolidated statements of comprehensive income (loss) is as follows:

(i) The $0.2 million increase in general and administrative expenses for the three months ended March 31, 2024, the $0.3 million increase for the three months ended June 30, 2024, the $0.6 million increase for the six months ended June 30, 2024, the $0.5 million increase for the three months ended September 30, 2024, and the $1.1 million increase for the

nine months ended September 30, 2024, are related to the adjustment for estimated state and local sales tax expense and for the related penalties on outstanding sales tax balances.

(ii) The $26 thousand increase in interest expense for the three months ended March 31, 2024, the $30 thousand increase for the three months ended June 30, 2024, the $56 thousand increase for the six months ended June 30, 2024, the $38 thousand increase for the three months ended September 30, 2024, and the $94 thousand increase for the nine months ended September 30, 2024, are related to the adjustment for estimated interest on outstanding state and local sales tax balances.

The tables below present the previously reported and restated cash flow data for the three months ended March 31, 2024, the six months ended June 30, 2024, and the nine months ended September 30, 2024. The restated amounts reflect the correction of the error described above. Contract liabilities are included in the interim tables below for clarity as the restated Condensed Consolidated Statement of Cash Flows for the year ended December 31, 2024, shows accrued expenses netted with contract liabilities.

(in thousands)		For the three months ended March 31, 2024		
Unaudited Condensed Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Loss		$ (4,528)	$ (270)	$ (4,798)
Accrued expenses	(i)	(20)	270	250
Contract liabilities		(22)	-	(22)
Net Cash Provided by Operating Activities		$ 1,100	$ -	$ 1,100

		For the six months ended June 30, 2024		
Unaudited Condensed Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Income (Loss)		$ 2,033	$ (645)	$ 1,388
Accrued expenses	(i)	328	645	973
Contract liabilities		41	-	41
Net Cash Provided by Operating Activities		$ 432	$ -	$ 432

		For the nine months ended September 30, 2024		
Unaudited Condensed Consolidated Statement of Cash Flows	Notes	As Previously Reported	Adjustment	As Restated
Net Loss		$ (18,624)	$ (1,153)	$ (19,777)
Accrued expenses	(i)	763	1,153	1,916
Contract liabilities		56	-	56
Net Cash Provided by Operating Activities		$ 1,714	$ -	$ 1,714

A description of the restatement adjustments in the consolidated statements of cash flows is as follows:

(i) The $0.3 million, $0.6 million, and $1.2 million increases in accrued expenses for the three months ended March 31, 2024, the six months ended June 30, 2024, and the nine months ended September 30, 2024, respectively, are related to accrued sales tax, and the related interest and penalties on outstanding sales tax balances.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

Item 9A. 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 December 31, 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 December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Management, with the participation of the Chief Executive Officer (principal executive officer) and the Chief Financial Officer (principal financial and accounting officer), evaluated the effectiveness of the Company's internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework (2013).

As previously disclosed, management has identified material weaknesses in the Company's internal control over financial reporting primarily related to insufficient accounting resources and technical expertise to appropriately analyze and apply U.S. GAAP, as well as deficiencies in the design and implementation of business process controls, including those related to revenue recognition and sales tax, and information technology controls. As a result of these material weaknesses, management concluded that the Company's internal control over financial reporting was not effective as of December 31, 2025.

Management continues to evaluate and implement remediation measures designed to address these material weaknesses and strengthen the Company's internal control environment.

Remediation Plan

Management is committed to remediating the material weaknesses in the Company's internal control over financial reporting and has implemented and continues to implement measures designed to strengthen the control environment. These efforts include enhancing technical accounting resources, formalizing and expanding internal control procedures over financial reporting, and improving oversight and documentation of key control activities.

The Company has engaged external advisors to assist with technical accounting matters, including valuation analyses related to complex financial instruments and derivatives. In addition, the Company has implemented governance, risk, and compliance software to support control documentation, monitoring, and testing activities.

The Company also plans to further strengthen its control environment by adding personnel, improving segregation of duties, and enhancing information technology general controls, including controls over the Company's enterprise resource planning systems. Management believes these actions will strengthen the Company's internal control framework; however, the material weaknesses will not be considered remediated until the applicable controls have been designed, implemented, and are operating effectively for a sufficient period, and management has concluded, through testing, that the controls are operating effectively.

Management will continue to evaluate and refine its remediation efforts and perform additional analyses and procedures to ensure that the Company's consolidated financial statements are prepared in accordance with U.S. GAAP while remediation activities remain in progress.

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 December 31, 2025, that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting, except as disclosed in "Remediation Plan" above.

Item 9B. OTHER INFORMATION

During the three months ended December 31, 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 Item 408(c) of Regulation S-K).

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. All financial statements

The following financial statements are included in this Annual Report on Form 10-K in Item 8 of Part II:

2. Financial statement schedules

No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

The exhibits below are furnished or filed and, as applicable, are incorporated by reference herein as part of this Annual Report on Form 10-K.

Exhibit No.	Description
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 3.01 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	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	Preferred Stock of the Company dated January 31, 2020 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on February 6, 2020).
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series 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).
3.10	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).
3.11	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).
3.12	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).
3.13	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).
3.14	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).
10.1∞	Amended and Restated 2006 Stock Option Incentive Plan of SANUWAVE Health, Inc. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on November 3, 2010).
10.2	Master Equipment Lease, dated January 26, 2018, by and among the Company and NFS Leasing, Inc. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on February 15, 2018).
10.3	Form of Registration Rights Agreement, dated August 5, 2022, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on August 8, 2022).
10.4	Registration Rights Agreement, dated November 14, 2022, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.70 to the Form S-1/A filed with the SEC on January 31, 2023).
10.5	Registration Rights Agreement, dated May 9, 2023, by and among the Company and certain lenders.
10.6∞	Executive Employment Agreement, effective May 23, 2023, by and between the Company and Morgan Frank (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on May 30, 2023).
10.7	Registration Rights Agreement, dated December 30, 2023, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on January 3, 2024).
10.8	Registration Rights Agreement, dated January 21, 2024, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on January 21, 2024).
10.9∞	Offer Letter of Peter Sorensen, dated March 26, 2024 (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on April 1, 2024).
10.10	Registration Rights Agreement, dated June 18, 2024, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on June 21, 2024).
10.21∞	SANUWAVE Health, Inc. 2024 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on August 9, 2024).
10.12	Registration Rights Agreement, dated October 16, 2024, by and among the Company and the purchasers identified on the signature pages thereto (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on October 18, 2024).

10.13∞	Form of Stock Option Award Agreement under the SANUWAVE Health, Inc. 2024 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on October 25, 2024).
10.14	Lease, effective as of March 27, 2025, between Sanuwave, Inc. and Henry Kumagai, Trustee of the Kumagai Family Trust U/A Dated May 11, 2010 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on March 31, 2025).
10.15	Credit Agreement, dated as of September 25, 2025, by and among Sanuwave Health, Inc., as a guarantor, Sanuwave, Inc., as a borrower, SanuWave Services, LLC, as a guarantor, the lenders from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on September 26, 2025).
10.16∞	Separation and Release Agreement, dated October 24, 2025, between Andrew Walko and the Company (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on October 30, 2025).
19.1*	SANUWAVE Health, Inc. Insider Trading Policy. (Incorporated by reference to Exhibit 19.1 to the Form 10-K filed with the SEC on March 20, 2025)
23.1*	Consent of Baker Tilly US, LLP, independent registered public accounting firm
23.2*	Consent of Marcum LLP, independent registered public accounting firm
24.1*	Power of Attorney (included on signatures page).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32.1*	Section 1350 Certification of the Chief Executive Officer.
32.2*	Section 1350 Certification of the Chief Financial Officer.
97.1*	SANUWAVE Health, Inc. Compensation Recovery Policy (Incorporated by reference to Exhibit 97.1 to the Form 10-K filed with the SEC on March 20, 2025).
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 with Interactive Data File

∞ Indicates management contract or compensatory plan or arrangement.
* Filed herewith
# Confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and submitted separately to the Securities and Exchange Commission.
β Confidential portions of this exhibit have been omitted as permitted by applicable regulations.

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of 15(d) 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: March 26, 2026

By: /s/ *Morgan Frank*
Name: Morgan Frank
Title: Chief Executive Officer

POWER OF ATTORNEY

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Morgan Frank and Peter Sorensen, and each of them, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or such person's substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

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

Signatures	Capacity	Date
By: /s/ *Morgan Frank* Name: Morgan Frank	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	March 26, 2026
By: /s/ *Peter Sorensen* Name: Peter Sorensen	Chief Financial Officer (principal financial and accounting officer)	March 26, 2026
By: */s/ Gregory Bazar* Name: Gregory Bazar	Director	March 26, 2026
By: */s/ Jeffrey Blizard* Name: Jeffrey Blizard	Director	March 26, 2026
By: */s/ Ian Miller* Name: Ian Miller	Director	March 26, 2026
By: */s/ James Tyler* Name: James Tyler	Director	March 26, 2026

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