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, 2022

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.)**
11495 Valley View Road **Eden Prairie, MN**	**55344**
(Address of Principal Executive Offices)	**(Zip Code)**

(770) 419-7525
Registrant's Telephone Number, Including Area Code

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

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

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

Common Stock, par value $0.001 per share

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 files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was $19.3 million.

As of March 28, 2023, there were issued and outstanding 558,637,651 shares of the registrant's common stock.

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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 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® and PACE®, success of future business development and acquisition activities; management's plans and objectives for future operations; industry trends; regulatory actions that could adversely affect the price of or demand for our approved products; our intellectual property portfolio; our business, marketing and manufacturing capacity and strategy; estimates regarding our capital requirements, the anticipated timing of the need for additional funds, and our expectations regarding future capital-raising transactions, including through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing agreements, or raising capital through the conversion of outstanding warrants or issuances of securities; product liability claims; economic conditions that could adversely affect the level of demand for or the cost of our products; timing of clinical studies and any eventual U.S. Food and Drug Administration (FDA) approval of our products; financial markets; the competitive environment; supplier and customer disputes; the potential impact of the COVID-19 pandemic on our business; 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 Securities and Exchange Commission (the "SEC") filings. These and many other factors could affect the Company's future financial condition and operating results and could cause actual results to differ materially from expectations based on forward-looking statements made in this document or elsewhere by the Company or on its behalf. The Company undertakes no obligation to revise or update any forward-looking statements.

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 restates the following previously issued Unaudited Consolidated Financial Statements, data, and related disclosures:

1. Our unaudited quarterly financial information for the quarter ended March 31, 2022, quarter and six months ended June 30, 2022, and quarter and nine months ended September 30, 2022, See Part II, Item 8.
2. Our management's discussion and analysis of financial condition and results of operations as of and for the quarters ended March 31, 2022, June 30, 2022, and September 30, 2022, see Part II, Item 7.

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. These transactions included shares issued for services, which caused general and administrative expense to be understated, and the sale of assets under a financing agreement, which a gain on sale was recognized and overstated. Also, during the preparation of this Annual Report on Form 10-K it was discovered that certain vendor invoices were not properly recorded, causing general and administrative expense to be understated in prior periods, interest calculation on senior debt, which caused interest expense to be understated, and an inventory adjustment was posted improperly, which caused cost of revenues to be understated.

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 aggregate, and concluded that the errors in aggregate were material to the Consolidated Statements of Comprehensive Loss for the quarters ending March 31, 2022, June 30, 2022, and September 30, 2022. Management restated the impacted financial statements for the quarters ended March 31, 2022, the quarter and six-months ending June 30, 2022, and the quarter and nine-months ending September 30, 2022.

Accordingly, we are filing these restatements to correct these material errors. The financial information for the periods indicated above that are included in the Company's Form 10-Qs, Current Reports on Form 8-K, and earnings, press releases and similar communications issued prior to the filing of this Annual Report should not be relied on and are superseded by this Annual Report.

Item 1. BUSINESS

Overview

The Company is an ultrasound and shock wave technology company using patented systems of noninvasive, high-energy, acoustic shock waves or low intensity and non-contact ultrasound for regenerative medicine and other applications. Our focus is regenerative medicine utilizing noninvasive, acoustic shock waves or ultrasound to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal, and vascular structures. Our two primary systems are UltraMIST® and PACE®. UltraMIST and PACE are the only two Food and Drug Administration (FDA) approved directed energy systems for wound healing.

The UltraMIST system provides, through a fluid mist, low-frequency, non-contact, and pain free ultrasound energy deep inside the wound bed that promotes healing from within. The ultrasound acoustic waves promote healing by reducing inflammation and bacteria in the wound bed, while also increasing the growth of new blood vessels to the area. The UltraMIST system treatment must be administered by a healthcare professional. This proprietary technology has been cleared by the FDA for the promotion of wound healing through wound cleansing and maintenance debridement combined with ultrasound energy deposited inside the wound that stimulated tissue regeneration.

The PACE systems, use acoustic waves generated by the Company's Pulsed Acoustic Cellular Expression (PACE) technology to converge at precise selected targets to produce an extremely short duration compression burst. The precise targeting of tissue with PACE® technology provides healthcare professionals with a tool to positively influence cellular form and function, which can result in pain relief, improved circulation, and tissue regeneration. The PACE® system treatment must be administered by a healthcare professional. The Company sells three PACE systems including:

- dermaPACE®: Used to treat Diabetic Foot Ulcers and other chronic wounds
- orthoPACE®: Used to treat acute musculoskeletal conditions
- Profile: Used to provide therapeutic treatment of musculoskeletal conditions

Our portfolio of wound treatment solutions provides patients with a noninvasive technology that boosts the body's normal healing and tissue regeneration processes. The Company is marketing its UltraMIST and PACE systems for usage primarily in the United States.

Regarding the non-contact and non-thermal low frequency ultrasound UltraMIST system, the Company is focused on the following:

- Growth and expansion of sales across the United States
- Improvement of the functionality and ease-of-use for both medical personnel and patients
- Find antibacterial and anti-biofilm solutions to replace the saline solution used to produce the mist used by this system to conduct the ultrasound toward its target, which, the Company believes would make the system more effective in treating bacterial infections associated with skin conditions
- Design new applicators capable of treating large skin conditions, for improved efficiency in such cases.

The Company is focused on further developing our PACE proprietary technology to activate healing in:

- Acute and chronic wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;
- Orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation or tendinopathies, speeding the healing of fractures (including nonunion or delayed-union conditions), improving bone density in osteoporosis, fusing bones in the extremities and spine, and other potential sports injury applications;
- Plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and
- Cardiovascular applications for removing plaque due to atherosclerosis, eliminating occlusions and blood clots, and improving heart muscle and cardiac valves performance.

In addition to healthcare uses, our high-energy, acoustic pressure shock waves, due to their powerful pressure gradients and localized cavitational effects, may have applications in secondary and tertiary oil exploitation, for cleaning industrial waters and food liquids, unclogging pipes and filtration systems, and finally for maintenance of industrial installations and underwater structures by disrupting biofilms formation and eliminating fouling. The Company intends to pursue these opportunities through licensing and/or partnership opportunities.

The worldwide spread of the COVID-19 virus resulted in a global slowdown of economic activity, which has been further impacted by the war in Ukraine and related sanctions. Due to the combination of the COVID-19 slowdown and the war in the Ukraine, the Company has experienced a disruption of our supply channels during the years ended December 31, 2022, and 2021. Also, the pandemic caused continued or additional actions by hospitals and clinics such as limiting elective procedures and treatments and limiting clinical trial activities and data monitoring. These factors have had a negative impact on our sales and our results of operations.

UltraMIST - Ultrasound Healing Therapy

UltraMIST is an FDA approved powerful, non-contact, non-thermal ultrasound therapy system used to promote healing in a wide range of wound types. The system never touches the wound surface making it pain free. UltraMIST promotes wound healing below the surface by modulating cell membranes to drive increased blood flow and capillary formation. It also reduces and removes a wide range of bacteria, including biofilms, while preserving healthy structures. UltraMIST is FDA approved to treat malaises such as diabetic foot ulcers, pressure ulcers, venous leg ulcers, deep tissue pressure injuries, and surgical wounds.

PACE Technology for Regenerative Medicine

Our PACE system candidates, including our dermaPACE System, deliver high-energy acoustic pressure shock waves to produce compressive and tensile stresses on cells and tissue structures. These mechanical stresses at the cellular level have been shown in pre-clinical work to promote angiogenic and positive modulated inflammatory responses, and quickly initiate the healing cascade. This has been shown in pre-clinical work to result in microcirculatory improvement, including increased perfusion and blood vessel widening, the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE procedures trigger the initiation of an accelerated and modulated inflammatory response that speeds wounds into proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help reinitiate the body’s own healing response. The Company believes our PACE technology is well suited for various applications due to its activation of a broad spectrum of cellular events critical for the initiation and progression of healing.

Currently, there are limited biological or mechanical therapies available to activate the healing and regeneration of skin, musculoskeletal tissue, and vascular structures. As baby boomers age, the incidence of their targeted diseases and musculoskeletal injuries and ailments will be far more prevalent. The Company believes that our pre-clinical and clinical studies suggest that our PACE technology will be effective in targeted applications. The Company anticipates that future clinical studies should lead to regulatory approval of our regenerative product candidates in the Americas, Middle East and Africa. If approved by the appropriate regulatory authorities, the Company believes that our product candidates will offer new, effective, and noninvasive (extracorporeal) treatment options in wound healing, orthopedic injuries, plastic/cosmetic uses and cardiovascular procedures, improving the quality of life for millions of patients suffering from injuries or deterioration of tissue, bones and vascular structures.

dermaPACE – Our Wound Care Shockwave Product

The Company is focused on the development of products that treat unmet medical needs in large market opportunities. Our FDA approval in the United States for our, dermaPACE system is the first step in providing an option to a currently unmet need in the treatment of diabetic foot ulcers. Diabetes is common, disabling, and deadly. In the United States, diabetes has reached epidemic proportions. Based on our research, foot ulcerations are one of the leading causes of hospitalization in diabetic patients and lead to billions of dollars in health care expenditures annually. dermaPACE is noninvasive and does not require anesthesia, making it a cost-effective, time-efficient, and painless approach to wound care. dermaPACE’s noninvasive treatments are designed to elicit the body’s own healing response and followed by simple standard of care dressing changes, are designed to allow for limited disruption to the patients’ normal lives and have no effect on mobility while their wounds heal.

DermaPACE has received the European CE Mark approval to treat acute and chronic defects of the skin and subcutaneous soft tissue, such as in the treatment of pressure ulcers, diabetic foot ulcers, burns, and traumatic and surgical wounds. The dermaPACE is also licensed for sale in Canada, Australia, New Zealand and South Korea. Additionally, our joint venture partner in Brazil, Diversa SA, received approval from the Brazilian Agência Nacional de Vigilância Sanitária (“National Health Surveillance Agency” or “ANVISA”) to market dermaPACE to treat diabetic foot ulcers in Brazil.

Developing Product Opportunities - Orthopedic

The orthoPACE system, which is intended for use in orthopedic, trauma and sports medicine indications, continues to be a viable and effective treatment solution in Europe and South Korea. The system features four types of applicators including a unique applicator that is less painful for some indications and may reduce or eliminate anesthesia for some patients. In the orthopedic setting, the orthoPACE system is being used to treat tendinopathies and acute and nonunion fractures, including the soft tissue surrounding the fracture to accelerate healing and prevent secondary complications and their associated treatment costs. Common examples of these injuries include extremity joint pain, torn rotator cuffs (shoulder), tennis elbow, Achilles’ tendon tears and torn meniscus cartilage in the knee. Injuries to these structures are very difficult to treat because the body has a limited natural ability to regenerate these kinds of tissues. Prior investigations and pre-clinical work indicate that PACE can positively affect the body’s inflammatory process and activate various cell types and may be an important adjunct to the management of sports medicine injuries. The Company plans to submit to the FDA a 510(k) seeking clearance for general indications to address this growing field.

Additionally, the Company has developed and introduced Profile by SANUWAVE as an immediately available solution for pain management in sports medicine and physical therapy in the U.S. market. Profile by SANUWAVE is a therapeutic massager intended for the relief of minor muscle aches and pains via SANUWAVE's Diffused Acoustic Pressure (DAP®) technology. DAP® delivers the beneficial, therapeutic field of the acoustic pressure waves without the impact and potential pain of a focused pulse. There is a significant need in the U.S. for pain management products and the Company believes the non-invasive delivery of therapeutic shockwaves for its treatment can help to serve this market.

Non-Medical Uses for Our Shockwave Technology

The Company believes there are also significant opportunities for our acoustic pressure shockwave technology in non-medical uses, including in the energy, water, food, and industrial markets.

Market Trends

The Company is focused on the development of regenerative medicine products that have the potential to address substantial unmet clinical needs across broad market indications. The Company believes there are limited therapeutic treatments currently available that directly and reproducibly activate healing processes in the areas in which the Company is focusing, particularly for wound care and repair of certain types of musculoskeletal conditions.

With the success of negative pressure wound therapy devices in the wound care market over the last decade and the recognition of the global epidemic associated with certain types of wounds, as well as deteriorating musculoskeletal conditions attributed to obesity, diabetes, vascular and heart disease, as well as sports injuries, the Company believes that Medicare and private insurers have become aware of the high costs and expenditures associated with the adjunctive therapies being utilized for wound healing and orthopedic conditions that have limited efficacies in full skin closure, or bone and tissue regeneration. The Company believes the wound healing and orthopedic markets are undergoing a transition, and market participants are interested in biological response activating devices that are applied noninvasively and seek to activate the body's own capabilities for regeneration of tissue at injury sites in a cost-effective manner.

Strategy

Our strategy is focused on the commercialization of our patented, non-invasive, and biological response-activating medical systems for the repair and regeneration of skin, musculoskeletal tissue, and vascular structures. Our wound care portfolio of regenerative medicine products and product candidates help restore the body's normal healing processes, by activating biologic signaling and angiogenic responses.

The key elements of our strategy include the following:

- Commercialize and support the domestic distribution of our UltraMIST and PACE systems to treat wounds;
- Reduce and normalize operating costs to support growth;
- Develop and commercialize our noninvasive biological response activating devices in the regenerative medicine area for the treatment of skin, musculoskeletal tissue, and vascular structures; and
- Support the global distribution of our products.

Scientific Advisors

The Company has established a network of scientific advisors that brings expertise in wound healing, orthopedics, cosmetics, clinical and scientific research, and FDA experience. The Company consults our scientific advisors on an as-needed basis on clinical and pre-clinical study design, product development, and clinical indications.

The Company pays consulting fees to certain members of our scientific advisory board for the services they provide to us, in addition to reimbursing them for incurred expenses. The amounts vary depending on the nature of the services.

Sales, Marketing and Distribution

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

Manufacturing

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

The Company is party to a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our products. Our generator boxes are manufactured in accordance with applicable quality standards and applicable industry and regulatory standards. The Company produces the applicators and applicator kits for our products. In addition, the Company programs and loads software for both the generator boxes and applicators and perform the final product testing and certifications internally.

The Company is party to a manufacturing supply agreement with Minnetronix Medical in St. Paul, MN, covering the generator and treatment wand components of our products. 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. The Company produces the applicators and applicator kits for our products.

Our facility in Eden Prairie, MN consists of 8,199 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, product candidates, 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. In general, our patents are effective ranging from 6 months to 16 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 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.

Under our license to HealthTronics, Inc., the Company reserves exclusive rights in our purchased portfolio as to orthopedic, tendinopathy, skin wounds, cardiac, dental, neural medical conditions and to all conditions in animals (the “Ortho Field”). HealthTronics receives field-exclusive and sublicensable rights under the purchased portfolio as to (1) certain HealthTronics lithotripsy devices in all fields other than the Ortho Field, and (2) all products in the treatment of renal, ureteral, gall stones and other urological conditions (the “Litho Field”). HealthTronics also receives non-exclusive and non-sublicensable rights in the purchased portfolio as to any products in all fields other than the Ortho Field and Litho Field.

Pursuant to mutual amendment and other assignment-back rights under the patent license agreement with HealthTronics, the Company are also a licensee of certain patents and patent applications that have been assigned to HealthTronics. The Company received a perpetual, non-exclusive and royalty-free license to nine issued foreign patents. Our non-exclusive license is subject to HealthTronics' sole discretion to further maintain any of the patents and pending applications assigned back to HealthTronics.

The Company operates in an industry characterized by extensive patent litigation. If the Company becomes involved in future litigation or any other adverse intellectual property proceeding, for example, as a result of an alleged infringement, or a third party alleging an earlier date of invention, the Company may have to spend significant amounts of money and time and, in the event of an adverse ruling, the Company could be subject to liability for damages, including treble damages, invalidation of our intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business, financial condition and results of operation. In addition, any claims relating to the infringement of third-party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation or lengthy governmental proceedings and could divert management's attention and resources and require us to enter into royalty or license agreements which are not advantageous, if available at all.

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), dermaPACE® (United States, European Community, Japan, South Korea, Switzerland, Taiwan, Canada, China, Brazil, Mexico, and under the Madrid Protocol), angioPACE® (European Community and United Kingdom), PACE® - Pulsed Acoustic Cellular Expression (United States, European Community, China, Hong Kong, Singapore, Switzerland, Taiwan, and Canada), orthoPACE® (United States, United Kingdom, and European Community), DAP® - Diffused Acoustic Pressure (United States and European Community), and Profile® (United States, European Community, and United Kingdom). Our newest trademark is 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 now 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 trademark registrations for: OssaTron® (United States), OSWT® (Switzerland) Evotron® (United States, Germany and Switzerland), Evotrode® (United States, Germany and Switzerland), Orthotripsy® (United States). The Company phased out the OssaTrode® (United States, Germany and Switzerland), Equitron® (United States and Switzerland). Reflectron® (Germany and Switzerland) and Reflectrode® (Germany and Switzerland), evoPACE® (Canada, Australia, European Community and Switzerland) trademarks, due to the fact that OssaTrode®, Equitron®, Reflectron® and Reflectrode® products are no longer available for sale in any market and evoPACE® is a product that was never commercialized.

Competition

The Company believes the advanced wound care market can benefit from our technology which up-regulates the biological factors that promote wound healing. Current medical technologies developed by Acelity L.P. Inc, (formerly Kinetic Concepts, Inc.) now owned by 3M, Organogenesis, Inc., Smith & Nephew plc, Derma Sciences, Inc., MiMedx Group, Inc., Osiris Therapeutics, Inc., Molnlycke Health Care, and Systagenix Wound Management (US), Inc. (now owned by Acelity) and Softwave Tissue Regeneration Technologies, manage wounds, but, in our opinion, do not provide the value proposition to the patients and care givers like our PACE technology has the potential to do. The leading medical device serving this market is the Vacuum Assisted Closure ("V.A.C.") System marketed by KCI. The V.A.C. is a negative pressure wound therapy device that applies suction to debride and manage wounds.

There are also several companies that market extracorporeal shockwave device products targeting lithotripsy and orthopedic markets, including Dornier MedTech, Storz Medical AG, Electro Medical Systems (EMS) S.A., Softwave Tissue Regneration Technologies, and CellSonic Medical which could ultimately pursue the wound care market. Nevertheless, the Company believes that the PACE systems have a competitive advantage over all of these existing technologies by achieving wound closure by means of a minimally invasive process through innate biological response to PACE technology.

Regarding the companies that use low frequency ultrasound that creates a pressure wave producing micro-strains due to mechanical forces that deform cell membrane and therefore promote healing, there are technologies developed by Arobella Medical LLC, NanoVibronix, Chattanooga, and EDAP TMS to manage wound care. However, these treatment devices or medical systems are different in design and mode of application of the ultrasound when compared to SANUWAVE's UltraMIST. The Company believes that UltraMIST has a competitive advantage over all of these existing technologies, due to broad medical indications, simplicity of use, wound healing results and the tolerability of the treatment by the patients, especially for painful wounds.

Developing and commercializing new products is highly competitive. The market is characterized by extensive research and clinical efforts and rapid technological change. The Company faces intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major pharmaceutical companies. The Company may be unable to respond to technological advances through the development and introduction of new products. Most of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources. These competitors may also be in the process of seeking FDA or other regulatory approvals, or patent protection, for new products. Our competitors may commercialize new products in advance of our products. Our products also face competition from numerous existing products and procedures, which currently are considered part of the standard of care. To compete effectively, our products will have to achieve widespread market acceptance.

Regulatory Matters

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 product candidates 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 product candidates 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 product candidates 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. In the United States, there is an annual requirement for submitting device reports for Class III/PMA devices, along with an associated fee. Currently, the Company is registered as a Small Business Manufacturer with the FDA and as such are 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) – 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: 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 will continue to participate in MDSAP as 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.

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 all five participating countries, most recently successfully completing a MDSAP recertification audit in September 2022. This certificate is valid for three years. Annual surveillance audits are required to maintain this certification.

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 payers 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. This does not apply to instances involving clinical trials. 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 payers. Third party payers 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 payers.

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 payers, that an adequate level of reimbursement will be available or that the third-party payers' 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 payers 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 payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

Confidentiality and Security of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996, as amended (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 PACE 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. We currently don't capture patient data through our PACE system.

In addition to the HIPAA Privacy Rule and Security Rule described above, we may become subject to state laws regarding the handling and disclosure of patient records and patient health information. These laws vary widely. Penalties for violation include sanctions against a laboratory's licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against us for a violation of a state's privacy laws. 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 Canada, Alberta Environment, 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, 2022, we had a total of 38 full time employees in the United States. Of these, five were engaged in research and development which 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 11495 Valleyview Road, Eden Prairie, MN 55344, and our main telephone number is (770) 419-7525.

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.

Restatement of Previously Issued Consolidated Financial Statements

On March 28, 2023, the Audit Committee (the "Audit Committee") of the Board of Directors of the Company, after consulting with management and the Company's independent registered public accounting firm, Marcum LLP, determined that the Company's consolidated financial statements included in its 2022 Annual Report on Form 10-K as of December 31, 2022 and the Company's previously issued condensed interim consolidated financial statements as of and for the interim periods in 2022 as filed in the Company's Quarterly Reports on Form 10-Q for the periods ended March 31, 2022, June 30, 2022, and September 30, 2022 should no longer be relied upon due to material misstatements that are described in greater detail in Note 3 and Note 22.

Any previously filed reports, press releases, earnings releases, or investor presentations or other communications describing the Company's financial statements and other related financial information covering the previously mentioned periods should no longer be relied upon.

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

Our recurring losses from operations and dependency upon future issuances of equity or other financing to fund ongoing operations have raised substantial doubt as to our ability to continue as a going concern. We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so, and/or the terms of any financings may not be advantageous to us.

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources for the commercialization of the PACE and will continue to research and develop the non-medical uses of the PACE technology, both of which will require additional capital resources. We incurred a net loss of $10.3 million and $27.3 million for the years ended December 31, 2022, and 2021, respectively. The operating losses and the events of default on the Company's notes payable indicate substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the filing of this Annual Report on Form 10-K.

The continuation of our business is dependent upon raising additional capital to fund operations. Management plans to obtain additional capital in 2023 through investments by strategic partners for market opportunities, or to raise capital through the conversion of outstanding warrants, issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders. In addition, there can be no assurances that our plans to obtain additional capital will be successful on the terms or timeline we expect, or at all. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or, if available, to obtain funds through financing transactions with unfavorable terms. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

We recently restated our financial statements for prior periods, which resulted in unanticipated costs and may adversely affect investor confidence, our stock price, our ability to raise capital in the future and our reputation and may result in stockholder litigation and regulatory actions.

On March 28, 2023, the Audit Committee of our Board of Directors, after discussion with management and with our independent registered public accounting firm, concluded that our previously issued consolidated financial statements as of and for the quarter and nine months ended September 30, 2022, quarter and six months ended June 30, 2022 and quarter ended March 31, 2022 (the "Affected Periods") should no longer be relied upon due to errors related to inaccurate application of US GAAP. As a result, we restated the financial statements for the Affected Periods.

Because of these restatements, we incurred unanticipated costs for accounting and legal fees, and the restatements may have the effect of eroding investor confidence in our company and our financial reporting and accounting practices and processes and may raise reputational issues for our business. The restatements may negatively impact the trading price of our securities and make it more difficult for us to raise capital on acceptable terms, or at all. In addition, the restatements and related material weaknesses in our internal control over financial reporting may also result in stockholder litigation against us, or adverse regulatory consequences, including investigations, penalties, or suspensions by the SEC. Any such regulatory consequences, litigation, claim or dispute, whether successful or not, could subject us to additional costs, divert the attention of our management, or impair our reputation. Each of these consequences could have a material adverse effect on our business, results of operations and financial condition.

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. These material weaknesses are as follows:

- Expertise and resources to analyze and properly apply U.S. GAAP to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distributing agreements with select vendors.

- A lack of internal resources to analyze and properly apply U.S. GAAP to accounting for financial instruments included in service agreements with select vendors.
- The Company has failed to design and implement controls around all accounting and IT processes and procedures and, as such, we believe that all its accounting and IT processes and procedures need to be re-designed and tested for operating effectiveness.

We are taking certain measures to remediate these material weaknesses described above as described 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, 2022. In addition, due to the material weaknesses in internal control over financial reporting, we have also determined that our disclosure controls and procedures were ineffective as of December 31, 2022. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

There can be no assurance as to when the material weaknesses will be remediated. At this time, we cannot provide an estimate of costs expected to be incurred in connection with implementing this remediation plan; however, 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 or avoid potential future material weaknesses to be identified in the future. 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, may result in additional 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.

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.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our capital stock, the issuance of promissory notes and convertible promissory notes, the issuance of notes payable to related parties, and product sales. We will 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. In addition, because of our private placements in August and November 2022, we are currently prohibited from incurring or guaranteeing most kinds of debt issued by public or private investors, which further constrains our options to raise capital. 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 financings and the amount of such financings. Factors that may cause our future capital requirements to be greater than anticipated or could accelerate our need for funds include, without limitation:

- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of any approved product;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- 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 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “PPACA”) on our operations;
- 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.

Our product candidates may not be commercialized successfully.

Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use.

We are subject to risks that:

- the reimbursement for our products is difficult to obtain or is too low, which can hinder the introduction and acceptance of our products in the market;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates.

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

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

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

For example, in 2019, Tissue Regeneration Technologies, LLC (DBAS Softwave) obtained clearance from the FDA for treatment of diabetic foot ulcers using non-focused shockwaves, as a 510(k) submission based on our PACE system *de novo* clearance.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may develop and commercialize pharmaceutical, biotechnology or medical devices that are safer or more effective, have fewer side effects or are less expensive than any products that we may develop.

We may not successfully establish and maintain licensing and/or partnership arrangements for our technology for non-medical uses, which could adversely affect our ability to develop and commercialize our non-medical technology.

Our strategy for the development, testing, manufacturing, and commercialization of our technology for non-medical uses generally relies on establishing and maintaining collaborations with licensors and other third parties. We may not be able to obtain, maintain or expand these or other licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to obtain, maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Furthermore, our licensing and collaboration agreements are subject to counterparty risk, and to the extent the licensors or other third parties that we enter into licensing, joint venture or other collaboration arrangements with face operational, regulatory or financial difficulties, and to the extent we are unable to find suitable alternative counterparties in a timely manner, if at all, our business and results of operations could be materially adversely affected. Any failure to obtain, maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition, or ability to develop and commercialize our technology for non-medical uses.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our technology for non-medical uses, possibly including the design and manufacture of product materials, the obtaining of regulatory or environmental approvals and the marketing and distribution of any successfully developed products. Our collaborators also may have or acquire rights to control aspects of our product development programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we may contemplate. In addition, if any of these collaborators withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

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 component, and the loss of any of these suppliers could result in a disruption in our production. If this were to occur, it may be difficult to arrange a replacement supplier because certain of these materials may only be available from one or a limited number of sources. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. In addition, some of our suppliers have been and will continue to be affected by supply chain problems resulting from the pandemic. Establishing additional or replacement suppliers for these materials may take a substantial period of time, as certain of these suppliers must be approved by regulatory authorities.

If we are unable to secure, on a timely basis, sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, 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.

We have entered into an agreement with companies owned by a current board member and stockholder that could delay or prevent an acquisition of our Company and could result in the dilution of our stockholders in the event of our change of control.

On February 13, 2018, we entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc. (“PSWC”) and Premier Shockwave, Inc. (“PS”), each of which is owned by a member of the Company’s board of directors and an existing stockholder of the Company. Among other terms, the agreement contains provisions whereby in the event of a change of control of the Company (as defined in the agreement), the stockholders of PSWC have the right and option to cause the Company to purchase all of the stock of PSWC, and whereby the Company has the right and option to purchase all issued and outstanding shares of PSWC, in each case based upon certain defined purchase price provisions and other terms. Such provision may have the effect of delaying or deterring a change in control of the Company, and as a result could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. In addition, in the event we do experience a change of control, such provision may cause dilution of our existing stockholders if PSWC exercises its option to require the Company to purchase all issued and outstanding shares of PSWC and the Company finances some or all of such purchase price through equity issuances.

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

As a small company with less than 40 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.

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.

A portion of our revenue comes from international sources, and we anticipate that we will continue to expand our overseas operations. 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.

As we expand internationally, our results of operations and cash flows will become increasingly 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.

The COVID-19 pandemic has materially and adversely affected our financial results.

The COVID-19 pandemic has affected many countries, including the United States and several European countries. The consequences of the COVID-19 pandemic adversely affect our ability to commercialize our products, ability to build inventory, increase our operating expenses, and has had a material adverse effect on our financial results. We have experienced a disruption of our supply channels during the years ended December 31, 2022, and 2021. Also, the pandemic caused continued or additional actions by hospitals and clinics such as limiting elective procedures and treatments and limiting clinical trial activities and data monitoring. These factors have had a negative impact on our sales and our results of operations and may continue to have a negative impact in the future.

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;
- 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 the affirmative vote of a majority of directors then in office, even if 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 product candidates, 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 and product candidates, 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 product candidates, 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 product candidates 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 product candidates, 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 payers, there may be no commercially viable markets for our approved products, or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payers affect the market for our approved products. The efficacy, safety, performance, and cost-effectiveness of our 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 payers 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 payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our approved products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our approved products would be impaired and our future revenues, if any, would be adversely affected.

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

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

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 payors 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 believe our operations comply with the Federal Anti-Kickback Statute, False Claims Act, and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the Federal Anti-Kickback Statute, 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 Privacy, Security and Breach Notification Regulations, 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 PACE business, we will in the future be a covered entity under HIPAA. We intend to ensure our policies and procedures continue to comply with the Privacy Rule, the Security Rule and the HIPAA statute as such regulations become applicable to our business and as such regulations are in effect at such time; however, 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.

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 Centers for Medicare & Medicaid Services 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 [and product candidates] 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 product candidates we want to commercialize. Further, patent applications in the United States that are not filed in other countries may not be published or generally are not published until at least 18 months after they are first filed, and patent applications in certain foreign countries generally are not published until many months after they are filed. Scientific and patent publication often occurs long after the date of the scientific developments disclosed in those publications. As a result, we cannot be certain that we will be the first creator of inventions covered by our patents or applications, or the first to file such patent applications. As a result, our issued patents and our patent applications could become subject to challenge by third parties that created such inventions or filed patent applications before us or our licensors, resulting in, among other things, interference proceedings in the United States Patent & 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 product candidates at all. We have devoted limited resources to identifying competing technologies that may have a competitive advantage relative to ours, especially those competing technologies that are not perceived as infringing on our intellectual property rights. In addition, the standards that courts use to interpret and enforce patent rights are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, we cannot be certain as to how much protection, if any, will be afforded by these patents with respect to our products if we, our licensees or our licensors attempt to enforce these patent rights and those rights are challenged in court.

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

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

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

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

The biotechnology, biopharmaceutical and medical device industries are characterized by 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 product candidates 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 product candidates 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.

There is currently a limited trading market for our common stock, and we cannot predict how liquid the market might become.

To date, there has been a limited trading market for our common stock, and we cannot predict how liquid the market for our common stock might become. Until January 30, 2023, our common stock was quoted on the OTC Pink, which is an inter-dealer market that provides significantly less liquidity than the New York Stock Exchange or the Nasdaq Stock Market. We are currently listed on the OTCQB.

The quotation of our common stock on the OTCQB does not assure that a meaningful, consistent, and liquid trading market exists. The market price for our common stock is subject to volatility and holders of our common stock may be unable to resell their shares at or near their original purchase price, or at any price. In the absence of an active trading market:

- investors may have difficulty buying and selling, or obtaining market quotations for our common stock;
- market visibility for our common stock may be limited; and
- a lack of visibility for our common stock may have a depressive effect on the market for our common stock.

Trading for our common stock is limited under the SEC's penny stock regulations, which has an adverse effect on the liquidity of our common stock.

The trading price of our common stock is less than $5.00 per share and, as a result, our common stock is considered a "penny stock," and trading in our common stock is subject to the requirements of Rule 15g-9 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Under this rule, broker-dealers who recommend low-priced securities to persons other than established customers and accredited investors must satisfy special sales practice requirements. Generally, the broker-dealer must make an individualized written suitability determination for the purchaser and receive the purchaser's written consent prior to the transaction.

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

As an issuer of "penny stock", the protection provided by the Federal securities laws relating to forward-looking statements does not apply to us.

Although Federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the Federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

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.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our board of directors has the right, without stockholder approval, to issue preferred stock with voting, dividend, conversion, liquidation, or other rights which could adversely affect the voting power and equity interest of the holders of common stock, which could be issued with the right to more than one vote per share, and could be utilized as a method of discouraging, delaying or preventing a change of control. The possible negative impact on takeover attempts could adversely affect the price of our common stock.

We have not sought an advisory stockholder vote to approve the compensation of our named executive officers.

Rule 14a-21 under the Exchange Act requires us to seek a separate stockholder advisory vote at our annual meeting at which directors are elected to approve the compensation of our named executive officers, not less frequently than once every three years (say-on-pay vote), and, at least once every six years, to seek a separate stockholder advisory vote on the frequency with which we will submit advisory say-on-pay votes to our stockholders (say-on-frequency vote). We have not submitted to our stockholders a say-on-pay vote to approve an advisory resolution regarding our compensation program for our named executive officers, or a say-on-frequency vote. Consequently, the board of directors has not considered the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers.

If the Company fails to comply with our SEC filing obligations, our stock may become subject to limitations or reduction in stock price, liquidity, or volume.

Rule 15c2-11 under the Exchange Act (the "Rule") governs the publication of quotations in over-the-counter ("OTC") markets. On September 16, 2020, the SEC adopted amendments to the Rule which prohibits broker-dealers from publishing or submitting for publication a quote for an issuer's securities unless they are based on current publicly available information about the issuer. The amended Rule also limits the Rule's "piggyback" exception, which allows broker-dealers to publish quotations for a security in reliance on the quotations of a broker-dealer that initially performed the information review required by the Rule, to issuers with current publicly available information or issuers that are up to date in their Exchange Act reports.

The practical impact of these changes requires us to maintain a level of periodic disclosure. However, we did not timely file with the SEC our Annual Report on Form 10-K for the year ended December 31, 2020 or our Quarterly Report on Form 10-Q for the quarters ended March 31, 2021 or June 30, 2021. As a result, our stock was removed from the OTC Bulletin Board on September 28, 2021, which limited the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market. Upon filing the Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, we were allowed to return to the OTC Pink and subsequently uplisted to the OTCQB. While trading on the OTCQB, and especially if we are removed from the OTCQB in the future, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our primary corporate and operations office is a leased facility in Eden Prairie, Minnesota, consisting of 8,199 square feet of space under a lease which expires on August 31, 2023. Under the terms of the lease, we pay monthly rent, subject to a 2.5% adjustment on an annual basis.

We also have a research and development office in a leased facility in Alpharetta, Georgia, consisting of 4,332 square feet of space under a lease that expires in July 2027.

Item 3. LEGAL PROCEEDINGS

We are engaged in various legal actions, claims and proceedings arising in the ordinary course of business, including claims related to breach of contracts and intellectual property matters resulting from our business activities. As with most actions such as these, an estimation of any possible and/or ultimate liability cannot always be determined.

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.

In May 2021, the Company received notification that it is not in compliance with the Biovance portion of the License Agreement with Celularity as discussed in Note 21 of our Financial Statements included in this Annual Report on Form 10-K. The Company has responded and asserted that the Company is not in breach and that the Supplier has breached various agreements. It is too early to determine the outcome of this matter. Any potential impact to the Company cannot be fully determined at this time.

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 OTCQB under the symbol "SNWV". The quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commissions, and may not necessarily represent actual transactions.

Holders of Common Stock

As of December 31, 2022, there were 548,737,651 shares of common stock outstanding and approximately 201 holders of record of the Company's common stock.

Dividends

The Company did not pay a cash dividend in 2022 or 2021. The Company intends to retain future earnings, if any, to finance the expansion of its business. The Company does not anticipate paying any cash dividends in the foreseeable future.

Item 6. [Reserved]

Not applicable.

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 years ended December 31, 2022, and 2021. You should read this discussion and analysis in conjunction with our consolidated financial statements and related notes thereto on December 31, 2022, and 2021, and for years 2022, and 2021, which are presented within Part II Item 8. "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. 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.

As discussed in Item 8. Financial Statements and Supplementary Data, in Note 3, we have restated our unaudited quarterly financial information for the quarter ended March 31, 2022, quarter and six months ended June 30, 2022, and quarter and nine months ended September 30, 2022. Accordingly, Management's Discussion and Analysis of Financial Condition and Results of Operations have been revised for the effects of this restatement.

Executive Summary

We realized significant revenue growth during the year ended December 31, 2022, with a 29% growth in revenue to $16.7 million for the year ended December 31, 2022, as compared to $13.0 million in 2021. Gross margins also increased to 74% from 62% in 2021. As the Company continues to focus on profitable growth, we have also reduced our operating loss by 37% to $9.0 million for the year ended December 31, 2022.

Net loss for the year ended December 31, 2022, was $10.3 million, or ($0.02) per basic and diluted share, compared to a net loss of $27.3 million, or ($0.05) per basic and diluted share, for the year ended December 31, 2021. We continue to focus on profitable growth and reduction in operating expenses. We believe these improvements sets the stage for additional growth as we head into 2023.

Results of Operations

The following table sets forth our consolidated statement of operations:

	For the Years Ended December 31,		Change	
(in thousands)	2022	2021	$	%
Revenue	16,742	$ 13,010	$ 3,732	29%
Cost of revenue	4,331	4,986	(655)	-13%
Gross margin	12,411	8,024	4,387	55%
Operating expenses:				
General and administrative	12,556	11,690	866	7%
Selling and marketing	7,474	8,591	(1,117)	-13%
Research and development	567	1,101	(534)	-49%
Depreciation and amortization	766	784	(18)	-2%
Operating loss	(8,952)	(14,142)	5,190	-37%
Other income (expense), net	(1,339)	(13,089)	11,750	-90%
Income tax expense	2	28	(26)	-93%
Net loss	$ (10,293)	$ (27,259)	$ 16,966	-62%

Revenue

Revenues for the year ended December 31, 2022, were $16.7 million, compared to $13.0 million for the same period in 2021, an increase of $3.7 million or 29%. The increase in net sales was primarily driven by the growth of the UltraMIST® system.

Cost of Revenue

Cost of revenues for the year ended December 31, 2022, was $4.3 million, compared to $5.0 million for the same period in 2021. Gross profit as a percentage of revenues was 74% for the year ended December 31, 2022, compared to 62% for the same period in 2021. The increase in gross profit as a percentage of revenues in 2022 was primarily due to the increase in sales of the UltraMIST system which has higher profit margins.

General and Administrative

General and administrative expenses for the year ended December 31, 2022, were $12.6 million as compared to $11.7 million for the same period in 2021, an increase of $0.9 million, or 7%. The increase in 2022 as compared to 2021, was primarily due to the higher legal costs related to patent work and securities work.

Selling and Marketing

Selling and marketing expenses for the year ended December 31, 2022, were $7.4 million as compared to $8.6 million for the same period in 2021, a decrease of $1.1 million, or 13%. The year-over-year decrease in sales and marketing expenses in 2022 was a result of cost saving initiatives taken by management.

Research and Development

Research and development expenses for the year ended December 31, 2022, were $0.6 million, compared to $1.1 million for the same period in 2021. The decrease in research and development expenses in 2022, as compared to 2021, was primarily due to the reduction in employees.

Other Income (Expense), net

Other expense, net consists of the following:

	2022	2021	$	%
Interest expense	$ (14,132)	$ (7,095)	$ (7,037)	99%
Change in fair value of derivatives	16,654	(2,622)	19,276	nm
Loss on issuance of debt	(3,434)	(3,572)	138	-4%
Gain/(loss) on extinguishment of debt	(418)	204	(622)	nm
Loss on foreign currency exchange	(9)	(4)	(5)	125%
Other expense, net	$ (1,339)	$ (13,089)	$ 11,750	-90%

nm - not meaningful

Other expense totaled $1.3 million for the year ended December 31, 2022, as compared $13.1 million for the same period in 2021, a decrease of $11.8 million or 90%. The decrease was primarily driven by an increased gain from the change in the fair value of derivative liability of $19.3 million, offset by increased interest expense of $7.0 million. The increased interest expense was the result of higher levels of debt outstanding during 2022, due to new issuances of convertible debt, compared with 2021. The change in fair value of the derivative liability relates to warrants issued during 2022 with the convertible debt.

Liquidity and Capital Resources

Since inception, the Company has incurred losses from operations each year. As of December 31, 2022, we had an accumulated deficit of $194.2 million. Historically, our operations have primarily been funded from the sale of capital stock, notes payable, and convertible debt securities. In August and November 2022, the Company raised new funding through two issuances of convertible notes payable with an aggregate principal amount of $20.2 million, consisting of $16.0 million in newly raised capital and $4.2 million in refinanced accrued expenses, previous notes payable, and fees. The convertible notes bear interest at a rate of 15% per annum and have a conversion price of $0.04 per share of common stock. The conversion price of the convertible notes is subject to adjustment, including if the Company issues or sells shares of common stock for a price per share less than the conversion price of the convertible notes or if the Company lists its shares of common stock on The Nasdaq Capital Market and the average volume weighted average price of such common stock for the five trading days preceding such listing is less than $0.04 per share; provided, however, that the conversion price shall never by less than $0.01.

The August and November 2022 financings also included two tranches of warrants, each of which is exercisable for an aggregate of 504.4 million shares of common stock at exercise prices of $0.04, and $0.067, respectively. The exercise price of the warrants is subject to adjustment, including if the Company issues or sells shares of common stock or Share Equivalents (as defined in the warrants) for an effective consideration price less than the exercise price of the warrants or if the Company lists its shares of common stock on The Nasdaq Capital Market and the average volume weighted average price of such common stock for the five trading days preceding such listing is less than $0.04 per share; provided, however, that the exercise price of the warrants shall never be less than $0.01 per share. The warrants have a five-year term.

In August 2020, the Company issued a Senior Secured Promissory Note Payable (the “Senior Secured Note”) to NH Expansion Credit Fund Holdings L.P. pursuant to which the Company had outstanding debt of $19.2 million as of December 31, 2022. Interest is charged at the greater of the prime rate or 3% plus 9%, paid quarterly. As of December 31, 2022, the Company is in default of the minimum liquidity provisions on the Senior Secured Note and, as a result, is accruing interest at the default interest rate of an incremental 5%. Interest expense on the Senior Secured Note totaled $5.9 million and $3.1 million for the years ended December 31, 2022, and 2021, respectively.

See Notes 10 and 11 to the consolidated financial statements in Part II Item 8. “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K for additional information regarding additional debt commitments, the convertible notes and accompanying warrants issued in August and November 2022, and the Senior Secured Note.

The following table presents summarized cash flow information:

	For the period ended December 31,	
(in thousands)	2022	2021
Cash flows used by operating activities	$ (17,169)	$ (6,409)
Cash flows provided by (used by) investing activities	$ 332	$ (529)
Cash flows provided by financing activities	$ 17,384	$ 5,121

Cash Flows from Operating Activities

The largest driver of cash flows from operations is the change in fair value of derivative liabilities connected to our convertible debt and warrants issued with the August and November 2022 financings. The Company recognized a gain on these liabilities of $16.7 million for the year ended December 31, 2022, and a loss totaling $2.6 million for the year ended December 31, 2021.

Cash Flows Provided by Financing Activities

Cash flows provided by financing activities increased primarily from the proceeds of $16.2 million from the issuance of the convertible promissory notes discussed above in this section, Liquidity and Capital Resources.

Going Concern

The continuation of our business is dependent upon raising additional capital to fund operations. We expect to devote substantial resources for the expansion and continued commercialization of our UltraMist and PACE systems, which will require additional capital resources. This, as well as the events of default on various notes payable, raise substantial doubt about our ability to continue as a going concern. Management plans to obtain additional capital in 2023 through the conversion of outstanding warrants, issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders. Although no assurances can be given that our plans to obtain additional capital will be successful or on the terms or timeline we expect, or at all, management believes that potential additional issuances of equity or other potential financing transactions, as discussed above, should provide the necessary funding for us over the next 12 months. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms.

The Company aims to achieve positive operating cash flows in the first half of 2023 as resources are devoted to grow revenue of the UltraMIST and PACE systems while managing operating spend. We believe that sales growth and positive operating cash flows will be enabled by investment in new leadership in sales, operations, and finance departments and strategically managing spend to enable growth.

See Note 2 to the consolidated financial statements in Part II Item 8. “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K for additional information on our ability to continue as a going concern.

Critical Accounting Policies and Estimates

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 4 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 policies and 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.

Derivative Liability’s from Embedded Conversion Options and Warrants

The Company classified certain convertible instruments as having embedded conversion options which qualified as derivative financial instruments to be separately accounted for. The Company also determined that certain warrants also qualified as derivative financial instruments. Various valuations models were used to estimate the fair value of these derivative financial instruments that are classified as derivative liabilities on the consolidated balance sheets. The models include subjective input assumptions that can materially affect the fair value estimates and as such are subject to uncertainty. The material assumptions for the selected subjective inputs have not changed for the reporting period, except for the expected volatility, which is estimated based on the actual volatility during the most recent historical period equal to the remaining life of the instruments.

Valuation of Intangible Assets and Goodwill

When we acquire a business, the assets acquired, and liabilities assumed are recorded at their respective fair values at the acquisition date. Goodwill is the excess of the purchase price over the estimated fair value of net assets of acquired businesses. Intangible assets primarily include patents, trademarks, and customer relationships. Determining the fair value of intangible assets acquired as part of a business combination requires us to make significant estimates. These estimates include the amount and timing of projected future cash flows of each project or technology, the discount rate used to discount those cash flows to present value, and the assessment of the asset’s life cycle. The estimates could be impacted by legal, technical, regulatory, economic, and competitive risks. The test for impairment of goodwill requires us to make several estimates to determine the fair value of the goodwill. Our estimates associated with the goodwill impairment test are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value. We assess the impairment of goodwill at the consolidated level annually. We also test definite-lived intangible assets for impairment when an event occurs, or circumstances change that would indicate the carrying amount of the assets or asset group may be impaired. We assess the impairment of indefinite-lived intangible assets annually and whenever an event occurs, or circumstances change that would indicate that the carrying amount may be impaired. Our assessment for goodwill and intangible assets impairment is based on future cash flows that require significant judgment with respect to future revenue and expense growth rates and other assumptions and estimates. We use estimates that are consistent with the highest and best use of the assets based on a market participant’s view of the assets being evaluated. Actual results may differ from our estimates due to several factors including, among others, changes in competitive conditions, regulatory changes, results of clinical trials, and changes in worldwide economic conditions.

Recently Issued Accounting Standards

Information regarding new accounting pronouncements is included in Note 4 to the consolidated financial statements in Part II Item 8. “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

Restatement of Interim Financial Statements

Results of Operations for the Three Months Ended March 31, 2022

(In thousands)	Three Months ended March 31,			
	2022 Restated	2021	$ Change	% Change
Revenue	3,195	2,116	1,079	51%
Cost of revenue	889	1,055	(166)	-16%
Gross Margin	2,306	1,061	1,245	117%
General and administrative	2,205	3,129	(924)	-30%
Selling and marketing	1,715	1,780	(65)	-4%
Research and development	166	354	(188)	-53%
Depreciation and amortization	176	192	(16)	-8%
Operating Loss	(1,956)	(4,394)	2,438	-55%
Other Expense	(3,145)	(527)	(2,618)	497%
Net Loss before income taxes	(5,101)	(4,921)	(180)	4%

Revenues and Gross Margin

Revenues for the three months ended March 31, 2022, were $3.2 million compared to $2.1 million for the same period in 2021, an increase of $1.1 million. The increase was driven by sales of UltraMIST® devices and single-use accessories.

Gross margin as a percentage of revenue increased to 72.2% from 50.1% during the first quarter of 2022 as compared with the first quarter of the prior year. The increase in gross margin percentages for the quarter was driven by higher sales of single-use accessories, which have a higher gross margin percentage, offset by the discontinuation of Biologics sales, which had a lower gross margin percentage.

Operating Loss

Operating loss for the three months ended March 31, 2022, totaled $2.0 million loss compared to $4.4 million for the same period in 2021. The decrease in operating loss is due to higher gross margin on UltraMIST as well as a decrease in operating expenses, primarily general and administrative and research and development.

General and administrative expenses decreased $0.9 million or 30% for the three-month period ended March 31, 2022, compared with the same period of 2021. This decrease was primarily due to registration penalties incurred in 2021 as well as a reduction in legal fees.

Research and development expenses decreased 53% to $166 thousand from $354 thousand during the first quarter of 2022 compared with the first quarter of 2021. The decrease was primarily due to lower employee compensation in the first quarter of 2022.

Other Expense

Other expense increased for the three months ended March 31, 2022, by $2.6 million to $3.1 million, as compared to $0.5 million for the same period in 2021. This increase in expenses is due to an increase in interest expense of $2.0 million, a loss on the issuance of debt of $3.4 million, partially offset by an increase in the change in fair value of derivatives of $2.8 million.

Results of Operations for the Three and Six Months Ended June 30, 2022

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands)	2022 Restated	2021	$ Change	% Change	2022 Restated	2021	$ Change	% Change
Revenue	3,882	2,909	973	33%	7,077	5,025	2,052	41%
Cost of revenues	1,096	1,048	48	5%	1,986	2,103	(117)	-6%
Gross Margin	2,786	1,861	925	50%	5,091	2,922	2,169	74%
General and administrative	3,730	2,923	807	28%	5,935	6,045	(110)	-2%
Selling and marketing	1,672	2,520	(848)	-34%	3,387	4,300	(913)	-21%
Research and development	171	272	(101)	-37%	337	626	(289)	-46%
Gain on disposal of assets	51	-	51	nm	51	-	51	nm
Depreciation and amortization	210	192	18	9%	386	391	(5)	-1%
Operating loss	(3,048)	(4,046)	998	-25%	(5,005)	(8,440)	3,435	-41%
Other income (expense), net	4,693	(4,563)	9,256	-203%	1,548	(5,090)	6,638	-130%
Net income (loss) before taxes	1,645	(8,609)	10,254	-119%	(3,457)	(13,530)	10,073	-74%

Revenues and Gross Margin

Revenues for the three month-period ended June 30, 2022, were $3.9 million compared to $2.9 million for the same period of 2021, an increase of $1.0 million. Revenues for the six months ended June 30, 2022, were $7.1 million compared to $5.0 million for the same period in 2021, an increase of $2.1 million. The increase for both periods was driven by the continued increased sales of UltraMIST® devices and single-use accessories.

Gross margin as a percentage of revenue increased to 71.8% from 64.0% during three-month period ended June 30, 2022, as compared with the same period of 2021, and to 71.9% from 58.1% during the six-month period ended June 30, 2022, as compared with the same period of 2021. The increase in gross margin percentages for the quarter was driven by higher sales of single-use accessories, which have a higher gross margin percentage, offset by the discontinuation of Biologics sales in the first quarter of 2022, which had a lower gross margin percentage.

Operating Loss

Operating loss decreased $1.0 million to $3.0 million for the three months ended June 30, 2022 as compared to $4.0 million for the same period in 2021. This was due to a decrease in selling and marketing and research and development, partially offset by an increase in general and administrative expenses. Operating loss decreased $3.4 million to $5.0 million for the six months ended June 30, 2022, as compared to $8.4 million for the same period in 2021. The decrease for the six months ended June 30, 2022, was due to a decrease in all operating expense categories.

General and administrative expenses increased $0.8 million to $3.7 million for the three-month periods ended June 30, 2022, as compared to $2.9 million for the same period in 2021. The increase is due to shares issued to consultants for services and an increase in legal fees for patents. General and administrative expenses decreased $0.1 million or 2% for the six-month period ended June 30, 2022, compared with the same period of 2021. The decrease for the six-month period ended June 30, 2022, was primarily due to a reduction in the registration penalties and legal fees that were incurred during the same period in 2021.

Selling and marketing expenses decreased by $0.8 million or 34% for the three-month period ended June 30, 2022, as compared with the same period of 2021. Selling and marketing expenses decreased by $913 thousand or 21% for the six-month period ended June 30, 2022, as compared with the same period of 2021. The decrease was primarily due to a reduction in sales and marketing headcount during 2022.

Research and development expenses decreased 37% to $0.2 million from $0.3 million during the three-months period ended June 30, 2022, as compared with the same period of 2021. Research and development expenses decreased 46% to $0.3 million from $0.6 million during the six-month period ended June 30, 2022, as compared with the same period of 2021. The decrease was primarily due to lower employee compensation in 2022.

Other Income (Expense), Net

Other income for the three months ended June 30, 2022, totaled $4.7 million as compared to $4.6 million expense for the same period in 2021. This change is due to a gain recognized in the change in fair value of derivative liabilities totaling $7.9 million as compared to a loss totaling $0.5 million for the same period in 2021. This was partially offset by an increase in interest expense for the three months ended June 30, 2022, of $1.5 million as compared to the same periods in 2021. Other income for the six months ended June 30, 2022, totaled $1.5million as compared to expense of $5.1 million for the same period in 2021. This increase in other income was due to the gain recognized for the change in fair value of derivative liabilities totaling $11.3 million for the six months ended June 30, 2022, as compared to $44 thousand for the same period in 2021. This was offset by an increase in interest expense totaling $3.5 million for the six months ended June 30, 2022.

Results of Operations for the Three and Nine Months Ended September 30, 2022

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2022 Restated	2021	$ Change	% Change	2022 Restated	2021	$ Change	% Change
Revenue	4,166	3,725	441	12%	11,242	8,750	2,492	28%
Cost of revenues	1,157	1,555	(398)	-26%	3,141	3,658	(517)	-14%
Gross Margin	3,009	2,170	839	39%	8,101	5,092	3,009	59%
General and administrative	3,498	2,864	634	22%	9,433	8,909	524	6%
Selling and marketing	1,650	2,150	(500)	-23%	5,037	6,450	(1,413)	-22%
Research and development	157	297	(140)	-47%	494	923	(429)	-46%
Gain on disposal of assets	-	-	-	nm	51	-	51	nm
Depreciation and amortization	189	194	(5)	-3%	575	585	(10)	-2%
Operating loss	(2,485)	(3,335)	850	-25%	(7,489)	(11,775)	4,286	-36%
Other income (expense), net	1,346	(911)	2,257	-248%	2,893	(6,001)	8,894	-148%
Net loss before taxes	(1,139)	(4,246)	3,107	-73%	(4,596)	(17,776)	13,180	-74%

Revenues and Gross Margin

Revenues for the three month-period ended September 30, 2022, were $4.2 million compared to $3.7 million for the same period of 2021, an increase of $0.4 million. Revenues for the nine months ended September 30, 2022, were $11.2 million compared to $8.7 million for the same period in 2021, an increase of $2.5 million. The increase for both periods was driven by the continued increased sales of UltraMIST® devices and single-use accessories.

Gross margin as a percentage of revenue increased to 72.2% from 58.3% during the three-month period ended September 30, 2022, as compared with the same period of 2021, and to 72.1% from 58.2% during the nine-month period ended September 30, 2022, as compared with the same period of 2021. The increases in gross margin percentage for the three and nine-months ended September 30, 2022, were driven by higher sales of single-use accessories, which have a higher gross margin percentage, and by the discontinuation of Biologics sales in the first quarter of 2022, which had a lower gross margin percentage.

Operating Loss

Operating loss for the three months ended September 30, 2022 decreased $0.9 million or 25% to $2.5 million, as compared to $3.3 million for the same period in 2021. Operating loss also decreased for the nine month period ending September 30, 2022, $4.3 million to $7.5 million operating loss, as compared to $11.8 million for the same period in 2021. The decreases in operating expenses are due to decreases in selling and marketing and research and development, offset by increases in general and administrative expenses.

General and administrative expenses increased $634 thousand or 22% for the three-month period ended September 30, 2022, compared with the same period of 2021. General and administrative expenses increased $524 thousand or 6% for the nine-month period ended September 30, 2022, compared with the same period of 2021. The increase for the three-months were primarily due to increased accounting costs as we transition from contractors to permanent employees. The increase for the nine-month period ended September 30, 2022, were primarily due to consulting fees incurred in the second quarter and additional legal fees for patents.

Selling and marketing expenses decreased by $500 thousand or 23% for the three-month period ended September 30, 2022, as compared with the same period of 2021. Selling and marketing expenses decreased by $1.4 million or 22% for the nine-month period ended September 30, 2022, as compared with the same period of 2021. The decrease was primarily due to a reduction in sales and marketing headcount during 2022 and increased cost management activities.

Research and development expenses decreased 47% to $157 thousand from $297 thousand during the three-month period ended September 30, 2022, as compared with the same period of 2021. Research and development expense as a percentage of revenue decreased from 8% during the three-month period ended September 30, 2021, to 4% for the same period in 2022. Expense decreased 46% to $494 thousand, or 4% of revenue, from $923 thousand, or 11% of revenue, during the nine-month period ended September 30, 2022, as compared with the same period of 2021. These decreases were primarily due to improved cost management in 2022.

Other Income (Expense), Net

Other income for the three and nine months ended September 30, 2022, totaled $1.3 million and $2.9 million, respectively. This is an increase in income as compared to expense for the three and nine months ended September 30, 2021, of $0.9 million and $6.0 million, respectively. The change in derivative liability fair value is the largest driver for the change from other expense in 2021 to other income in 2022. The gain on derivative liabilities totaled $5.3 million and $16.6 million for the three and nine months ended September 30, 2022, respectively. As compared to $1.6 million for the three and nine months ended September 30, 2021, respectively. This was offset by increased interest expense, due to financings.

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.

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Item 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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 sheets of SANUWAVE Health, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of comprehensive loss, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring losses and needs to raise additional funds to meet its obligations and sustain its operations and the occurrence of the events of default on the Company's debt. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated 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 audits. 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 audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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 audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Financial Instruments (2022 Convertible Promissory Notes and Warrant Liability)

Critical Audit Matter Description

As described in Notes 11 and 13 to the consolidated financial statements, the Company entered into a Securities Purchase Agreements for the sale in a private placement of (i) Future Advance Convertible Promissory Notes in an aggregate principal amount of $16.2 million in August and $4.0 million in November, (ii) Common Stock Purchase Warrants to purchase 504.4 million shares of common stock with an exercise price of $0.067 per share and (iii) Common Stock Purchase Warrants to purchase 504.4 million shares of common stock with an exercise price of $0.04 per share. The Company determined certain embedded conversion features associated with the 2022 Convertible Promissory Notes were required to be bifurcated and recorded at fair value. The warrants issued in connection with the 2022 Convertible Promissory Notes were recorded at fair value. The Company utilized the Black-Scholes model to determine the fair value of the embedded conversion option and warrant liability which consist of all liability warrants utilizing key inputs including discounted stock price and implied volatility.

The principal considerations for our determination that the valuation of the 2022 Convertible Promissory Notes and Warrant Liability is a critical audit matter are the significant judgment by management in determining the fair value of the embedded conversion option and warrant liability; this in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to the discounted stock price and implied volatility. Also, the audit effort involved the use of professionals with specialized skill and knowledge.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures related to the valuation of the 2022 Convertible Promissory Notes and Warrant Liability included the following, among others:

- We obtained an understanding of the design of the Company's controls over the valuation of the 2022 Convertible Promissory Notes and Warrant Liability, including controls over management's review of the valuation model and the significant assumptions used in determining the fair value of the embedded conversion option of the 2022 Convertible Promissory Notes and Warrant Liability.

- With assistance of our valuation specialists, we audited the fair value of the embedded conversion option and warrant liability, valuation methodology, and key assumptions used in determining the fair value of the embedded conversion option of the 2022 Convertible Promissory Notes and Warrant Liability by:

    a. Evaluating the appropriateness of the valuation model and techniques used in determining the fair value;
    b. Assessing the significant valuation assumption inputs of discounted stock price and implied volatility are consistent with those that would be used by market participants through the testing of source information, checking the mathematical accuracy of the calculation, and developing independent estimates and comparing to those selected by management, where applicable; and
    c. Recalculating the fair value that management arrived to verify it was reasonable.

- We audited the completeness and accuracy of the underlying data supporting the significant valuation assumption inputs.

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2018.

New York, NY
March 31, 2023

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2022 and 2021

(In thousands, except share data)	2022	2021
ASSETS		
Current Assets:		
Cash	$ 1,153	$ 619
Accounts receivable, net of allowance of $1,037 in 2022 and $785 in 2021	4,029	2,415
Inventory	868	1,040
Prepaid expenses and other current assets	570	326
Total Current Assets	6,620	4,400
Non-Current Assets:		
Property, equipment and right of use assets, net	750	1,012
Intangible assets, net	5,137	5,841
Goodwill	7,260	7,260
Other assets	106	106
Total Non-Current Assets	13,253	14,219
Total Assets	$ 19,873	$ 18,619
LIABILITIES		
Current Liabilities:		
Senior secured debt, in default	$ 14,416	$ 11,586
Convertible promissory notes	16,713	11,601
Convertible promissory note, related parties	7,409	1,596
Factoring liabilities	2,130	2,183
Accounts payable	4,400	7,644
Accrued expenses	8,512	8,641
Warrant liability	1,416	9,614
Current portion of SBA loans	-	158
Accrued interest	4,052	2,521
Accrued interest, related parties	788	289
Current portion of contract liabilities	60	48
Other	291	382
Total Current Liabilities	60,187	56,263
Non-Current Liabilities:		
SBA loans	-	875
Contract liabilities	230	293
Lease liabilities	438	118
Deferred tax liability	28	28
Total Non-Current Liabilities	696	1,314
Total Liabilities	$ 60,883	$ 57,577
Commitments and Contingencies (Footnote 21)		
STOCKHOLDERS' 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 issues and outstanding at 2022 and 2021	$ -	$ -
Common stock, par value $0.001, 2,500,000,000 shares authorized, 548,737,651 and 481,619,621 issued and outstanding at 2022 and 2021, respectively	549	482
Additional paid-in capital	152,750	144,582
Accumulated deficit	(194,242)	(183,949)
Accumulated other comprehensive loss	(67)	(73)
Total Stockholders' Deficit	(41,010)	(38,958)
Total Liabilities and Stockholders' Deficit	$ 19,873	$ 18,619

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
Years ended December 31, 2022 and 2021

(In thousands, except share and per share data)	2022	2021
Revenue	$ 16,742	$ 13,010
Cost of revenues	4,331	4,986
Gross Margin	12,411	8,024
Operating Expenses:		
General and administrative	12,556	11,690
Selling and marketing	7,474	8,591
Research and development	567	1,101
Depreciation and amortization	766	784
Total Operating Expenses	21,363	22,166
Operating Loss	(8,952)	(14,142)
Other Income (Expense)		
Interest expense	(12,771)	(6,883)
Interest expense, related party	(1,361)	(212)
Change in fair value of derivative liabilities	16,654	(2,622)
Loss on issuance of debt	(3,434)	(3,572)
Gain/(loss) on extinguishment of debt	(418)	204
Loss on foreign currency exchange	(9)	(4)
Total Other Expense	(1,339)	(13,089)
Net Loss Before Income Taxes	(10,291)	(27,231)
Income tax expense	2	28
Net Loss	$ (10,293)	$ (27,259)
Other Comprehensive Loss		
Foreign currency translation adjustments	6	(11)
Total Comprehensive Loss	$ (10,287)	$ (27,270)
Loss per Share:		
Net loss per share, basic and diluted	$ (0.02)	$ (0.05)
Weighted average shares outstanding, basic and diluted	549,470,787	518,355,642

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

(In thousands except share data)

	Common Stock					
	Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balances as of December 31, 2020	470,694,621	$ 471	$ 142,563	$ (156,690)	$ (62)	$ (13,718)
Cashless warrant exercise	10,925,000	11	(11)	-	-	-
Reclassification of warrant liability due to cashless warrant exercise	-	-	2,030	-	-	2,030
Net loss	-	-	-	(27,259)	-	(27,259)
Foreign currency translation adjustment	-	-	-	-	(11)	(11)
Balances as of December 31, 2021	481,619,621	$ 482	$ 144,582	$ (183,949)	$ (73)	$ (38,958)
Cashless warrant exercise	14,000,000	$ 14	$ 2,152	$ -	$ -	$ 2,166
Warrant exercise	909,091	1	99	-	-	100
Shares issued in conjunction with senior note	20,666,993	20	3,700	-	-	3,720
Shares issued for settlement of debt and warrants	19,444,446	20	1,341	-	-	1,361
Shares issued for services	12,097,500	12	876	-	-	888
Net loss	-	-	-	(10,293)	-	(10,293)
Foreign currency translation adjustment	-	-	-	-	6	6
Balance as of December 31, 2022	548,737,651	$ 549	$ 152,750	$ (194,242)	$ (67)	$ (41,010)

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2022 and 2021

(In thousands)	2022	2021
Cash Flows - Operating Activities:		
Net loss	$ (10,293)	$ (27,259)
Adjustments to reconcile net loss to net cash used by operating activities		
Depreciation and amortization	952	1,236
Bad debt expense	253	442
Shares issued for services	888	-
Gain/loss on extinguishment of debt	418	(204)
Income tax expense	2	28
Change in fair value of derivative liabilites	(16,654)	2,622
Loss on issuance of debt	3,434	3,572
Amortization of debt issuance and debt discounts	4,950	3,226
Changes in operating assets and liablities:		
Accounts receivable	(1,748)	(395)
Inventory, prepaid expenses and other assets	(72)	1,687
Accounts payable	(2,550)	3,181
Accrued interest and accrued interest, related parties	3,182	1,718
Accrued expenses and contract liabilities	69	3,737
Net Cash Used by Operating Activities	(17,169)	(6,409)
Cash Flows - Investing Activites		
Purchase (proceeds from sale) of property and equipment	332	(529)
Net Cash Flows Used by Investing Activities	332	(529)
Cash Flows - Financing Activities		
Proceeds from convertible promisorry notes	16,227	1,928
Proceeds from SBA loans	-	1,033
Proceeds from senior secured promissory note	2,940	940
Proceeds from factoring	695	1,737
Proceeds from warrant exercises	100	-
Proceeds from short term borrowings	640	175
Repayments of debt principal	(2,981)	(493)
Principal payments on finance leases	(237)	(199)
Net Cash Flows Provided by Financing Activities	17,384	5,121
Effect of Exchange Rates on Cash	(13)	(1)
Net Change in Cash During Period	534	(1,818)
Cash at Beginning of Period	619	2,437
Cash at End of Period	$ 1,153	$ 619
Supplemental Information:		
Cash paid for interest	$ 3,712	$ 2,580
Non-Cash Investing and Financing Activities:		
Reclassification of warrant liabilities to equity due to cashless warrant exercise	$ 2,166	$ 2,030
Settlement of debt and warrants with stock	1,361	-
Working capital balances refinanced into convertible promissory notes	2,363	-
Embedded conversion feature on convertible debt	2,760	4,138
Common shares issued in conjunction with senior secured debt	3,720	-
Warrant issuance in conjunction with advances on future cash receipts	-	1,227
Warrant issuance in conjunction with convertible notes	1,708	1,055

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2022 and 2021

1. Nature of the Business and Basis of Presentation

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

Basis of Presentation **-** The accompanying 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"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

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 loss in the consolidated statements of comprehensive loss and as cumulative translation adjustments in accumulated other comprehensive loss in the consolidated balance sheets.

Segment information **-** We have determined that we have one operating segment. Our revenues are primarily generated from sales in the United States. All significant expenses are generated, and all significant assets are located in the United States.

Reclassification **-** Certain accounts in the prior period consolidated financial statements 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. Going Concern

Our recurring losses from operations and dependency upon future issuances of equity or other financing to fund ongoing operations have raised substantial doubt as to our ability to continue as a going concern. We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so, and/or the terms of any financings may not be advantageous to us.

The continuation of our business is dependent upon raising additional capital. We expect to devote substantial resources for the expansion and continued commercialization of our UltraMIST and PACE systems which will require additional capital resources. The operating losses and the events of default on the Company's notes payable indicate substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the filing of this Annual Report on Form 10-K.

Management's plans are to obtain additional capital in 2023 through the conversion of outstanding warrants, issuance of common or preferred stock, securities convertible into common stock, or secured or unsecured debt. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions if obtained as discussed above should provide the necessary funding for us. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or obtain funds through financing transactions with unfavorable terms.

The accompanying consolidated financial statements have been prepared in conformity with U.S. GAAP, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the consolidated financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty. Our consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

3. Restatement of Previously Issued Financial Statements

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. These transactions included shares issued for services, which caused general and administrative expense to be understated, and the sale of assets under a financing agreement, which a gain on sale was recognized and overstated. Also, during the preparation of this Annual Report on Form 10-K it was discovered that certain vendor invoices were not properly recorded, causing general and administrative expense to be understated in prior periods, interest calculation on senior debt, which caused interest expense to be understated, and an inventory adjustment was posted improperly, which caused cost of revenues to be understated.

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 aggregate, and concluded that the errors were material to the Consolidated Financial Statements for the quarters ending March 31, 2022, June 30, 2022, and September 30, 2022. Management restated the impacted financial statements for the quarters ended March 31, 2022, the quarter and six-months ending June 30, 2022, and the quarter and nine-months ending September 30, 2022. Refer to Note 22 for restated quarterly financial statements.

4. 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 doubtful accounts, the net realizable value of inventory, fair value of goodwill and intangible assets, the determination of the valuation allowances for deferred taxes, estimated fair value of stock-based compensation, and the estimated fair value of embedded derivatives, including warrants and embedded conversion options.

Accounts receivable — Accounts receivable are stated at the amount management expects to collect from outstanding balances. Management provides for probable uncollectible amounts through a charge to earnings based on its assessment of the current status of individual accounts. Receivables are generally considered past due if greater than 60 days old. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the allowance for doubtful accounts. 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.

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

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 Accounting Standards Codification (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 accumulated 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, 2022, and 2021.

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 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 determines whether an arrangement is a lease at inception. When lease arrangements include lease and non-lease components, the Company accounts for lease and non-lease components (e.g. common area maintenance) separately based on their relative standalone prices.

For leases where the Company is the lessee, Right of Use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases did not provide an implicit interest rate, the Company used the equivalent borrowing rate for a secured financing with the term of equal to the remaining life of the lease at inception.

Any lease arrangements with an initial term of 12 months or less are not recorded on our consolidated balance sheets, and the Company recognizes lease costs for these lease arrangements on a straight-line basis over the lease term. In the event a lease arrangement would provide us with options to exercise one or more renewal terms or to terminate the lease arrangement, we would include these options when we are reasonably certain to exercise them in the lease term used to establish ROU assets and lease liabilities. None of our lease agreements include an option to purchase the leased asset, residual value guarantees, or material restrictive covenants.

The Company has other lease arrangements that are adjusted periodically based on an inflation index or rate. The future variability of these payments and adjustments are unknown, and therefore they are not included as minimum lease payments used to determine ROU assets and lease liabilities. Variable rental payments are recognized in the period in which the obligation is incurred.

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.

Sequencing policy – The Company follows a sequencing policy for which in the event partial reclassifications of contracts subject to ASC Topic 815-40-25, *Derivatives and Hedging*, is necessary, due to the Company's inability to demonstrate it has sufficient authorized shares, shares will be allocated based on earliest issuance date of potentially dilutive instruments with the earliest grants receiving first allocation of shares.

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 loss. This debt discount is reported as a reduction of the related debt liability.

Contract Liabilities – Device product sales are bundled with an initial one-year warranty and the Company offers a separately priced multi-year warranty. Because the warranty represents an obligation, revenue is deferred as a contract liability and recognized over the time that the Company satisfies its performance obligations, which is generally the warranty term.

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 recognizes revenue primarily from the following types of contracts:

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

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

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

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs incurred have been recorded in cost of goods sold totaled $324 thousand and $377 thousand for the years ended December 31, 2022, and 2021, 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 uses the fair value method of accounting for its employee stock option program. Stock-based compensation expense for all stock-based payment awards is based on the estimated fair value of the award measured on the grant date. The Company recognizes the estimated fair value of the award as compensation cost on a straight-line basis over the requisite service period of the award, which is generally the option vesting term. The Company generally issues new shares of common stock to satisfy option and warrant exercises.

The expected life of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted calculated under the simplified method. The risk-free rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of the grant. The expected volatility is based on the average volatility of the Company's common stock. The expected dividend yield is based on our historical dividend experience, however, since our inception, we have not declared dividends. Forfeitures are recognized as they occur.

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.

Recent Accounting Pronouncements –

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which was subsequently revised by ASU 2018-19. The ASU introduces a new model for assessing impairment of most financial assets. Entities will be required to use a forward-looking expected loss model, which will replace the current incurred loss model, resulting in earlier recognition of allowance for losses. The ASU is effective for annual reporting periods beginning after January 2023 with early adoption permitted. The Company is currently evaluating the impact of ASU 2016-13 on its consolidated financial statements.

5. Loss per share

The net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares outstanding for the years ended December 31, 2022, and 2021. In accordance with ASC Topic 260-10-45-13, *Earnings Per Share*, the weighted average of number of shares outstanding includes outstanding common stock and shares issuable for nominal consideration. Accordingly, warrants issued with a $0.01 per share exercise price, are included in weighted average shares outstanding as follows:

(in thousands)	December 31, 2022	December 31, 2021
Common shares	526,530	481,620
Common shares issuable assuming exercise of nominally priced warrants	22,941	36,736
Weighted Average Shares Outstanding	549,471	518,356

Diluted net loss per share would be 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 years ended December 31, 2022, and 2021, all potentially dilutive shares 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, 2022	December 31, 2021
Common stock options	21,246	31,760
Common stock purchase warrants	1,186,522	168,192
Convertible notes payable, including interest	603,425	90,380
	1,811,193	290,332

6. Inventory

Inventory consisted of the following:

(in thousands)	December 31, 2022	December 31, 2021
Finished goods	$ 570	$ 343
Parts and accessories	641	931
Reserve for slow moving inventory	(343)	(234)
Total Inventory	$ 868	$ 1,040

7. Intangible Assets

Carrying value of intangible assets consist of the following:

	December 31, 2022		December 31, 2021		Weighted-Average Useful Life (in years)
(in thousands)	Gross	Accumulated Amortization	Gross	Accumulated Amortization	
Definite-lived Intangibles					
Customer relationships	$ 3,820	$ (1,308)	$ 3,820	$ (763)	2.9
Patent	2,312	(292)	2,312	(171)	6.4
Tradenames	693	(88)	693	(50)	1.9
Intangible Assets	$ 6,825	$ (1,688)	$ 6,825	$ (984)	3.8

Amortization expense for each of the years ended December 31, 2022, and 2021 totaled $704 thousand. Future amortization expense is expected to be the following (dollars in thousands):

Year ended December 31,	Amortization
2023	704
2024	704
2025	704
2026	704
2027	487

8. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	December 31, 2022	December 31, 2021
Registration penalties	$ 1,583	$ 1,950
License fees	892	893
Board of directors fees	415	507
Employee compensation	4,585	4,247
Other	1,037	1,044
Total Accrued Expenses	$ 8,512	$ 8,641

9. Factoring Liabilities

In June 2021, the Company entered into a factoring agreement with an unrelated third party, pursuant to which the Company may sell certain of its accounts receivables for 86.25% of the value of the receivable. Advances available under the facility are capped at the lesser of $3.0 million or a formula amount, as defined in the agreement. Interest on advances is assessed at a fixed amount upon funding, which is equivalent to an annualized rate of 15.0% for the first 30 days, and daily thereafter at an annualized rate of 14.4%. The agreement's term is one month and automatically renews for additional one-month periods, unless either party provides 30 days' notice of termination. The accounts receivable is sold with recourse back to the Company, therefore, the Company accounts for the arrangement as traditional financing.

(In thousands)	December 31, 2022	December 31, 2021
Receivables transferred	$ 2,564	$ 2,026
Reserve amount held	(434)	(289)
Traditional factoring liability	2,130	1,737
Advances on future cash receipts	-	446
Factoring liability	$ 2,130	$ 2,183

10. Senior Secured Debt, in Default

The following table summarizes outstanding senior secured debt:

	December 31, 2022			December 31, 2021		
(In thousands)	Principal	Debt Discount	Carrying Value	Principal	Debt Discount	Carrying Value
Senior secured debt	$ 19,211	$ (4,795)	$ 14,416	$ 15,000	$ (3,414)	$ 11,586

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

In February 2022, the Company entered into a Second Amendment to Note and Warrant Purchase and Security Agreement (the "Second NWPSA") for $3.0 million, for a total of $18.0 million outstanding. Along with the issuance of the note, the Company also issued warrants to purchase 16.2 million shares of common stock with an exercise price of $0.18 and 20.6 million shares of common stock. Since the combined fair value of the warrants and common stock issued as part of the Second NWPSA exceeded the face value of the note, the additional amount beyond the face value was recorded as a loss on issuance totaling $3.4 million.

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

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

As of December 31, 2022, the Company is in default of the minimum liquidity provisions in the Senior Secured Note and, as a result, it is classified in current liabilities in the accompanying consolidated balance sheets. The Company is accruing interest at the default interest rate of an incremental 5%.

The debt issuance costs, and debt discount related to the Senior Secured Note were capitalized as a reduction in the principal amount and are being amortized to interest expense over the life of the Senior Secured Note. The amortization of the debt issuance costs and debt discount, included in interest expense, for the years ended December 31, 2022, and 2021, totaled $1.6 million and $910 thousand, respectively. Accrued interest related to the Senior Secured Note was $1.9 million and $1.6 million on December 31, 2022, and December 31, 2021, respectively. Interest expense on the Senior Secured Note totaled $5.9 million and $3.1 million for the years ended December 31, 2022, and 2021, respectively.

11. Convertible Promissory Notes and Convertible Promissory Notes, Related Parties

	December 31, 2022				
(In thousands, except conversion price)	Conversion Price	Principal	Debt Discount	Conversion Option	Carrying Value
Acquisition convertible promissory note, in default	$ 0.10	$ 4,000	$ -	$ -	$ 4,000
Convertible promissory note, related party, in default	$ 0.10	1,373	-	-	1,373
2022 Convertible notes payable	$ 0.04	13,660	(2,532)	1,585	12,713
2022 Convertible notes payable, related parties	$ 0.04	6,515	(1,234)	755	6,036
Total Convertible promissory notes		$ 25,548	$ (3,766)	$ 2,340	$ 24,122

	December 31, 2021				
(In thousands, except conversion price)	Conversion Price	Principal	Debt Discount	Conversion Option	Carrying Value
2021 Convertible promissory notes payable	$ 0.10	$ 2,446	$ (1,100)	$ 6,255	$ 7,601
Acquisition convertible promissory note, in default	$ 0.10	4,000	-	-	4,000
Convertible promissory note payable, related parties, in default	$ 0.10	1,596	-	-	1,596
Total Convertible Promissory Notes		$ 8,042	$ (1,100)	$ 6,255	$ 13,197

2022 Convertible Notes Payable and 2022 Convertible Notes Payable, Related Parties - In August 2022 and November 2022, the Company entered into a 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 and $4.0 million in November, (ii) Common Stock Purchase Warrants to purchase an additional 504.4 million shares of common stock with an exercise price of $0.067 per share and (iii) Common Stock Purchase Warrants to purchase an additional 504.4 million shares of common stock with an exercise price of $0.04 per share. The Company paid issuance costs totaling approximately $1.4 million. Interest expense for the year ended December 31, 2022, totaled $4.4 million, $1.2 million in contractual interest expense and $3.2 million in amortization of debt discount and issuance costs.

Pursuant to the Notes, the Company promised to pay in cash and/or in shares of common stock, at a conversion price of $0.04 (the "Conversion Price"), the principal amount and interest at a rate of 15% per annum on any outstanding principal. The Conversion Price of the Notes is subject to adjustment, including if the Company issues or sells shares of common stock for a price per share less than the Conversion Price of the Notes or if the Company lists its shares of common stock on The Nasdaq Capital Market and the average volume weighted average price of such common stock for the five trading days preceding such listing is less than $0.04 per share; provided, however, that the Conversion Price shall never by less than $0.01. The Notes contain customary events of default and covenants, including limitations on incurrences of indebtedness and liens. In addition, pursuant to the Notes, the Company agreed to reduce its outstanding shares via a reverse stock split to provide the number of authorized and unissued shares of common stock sufficient to permit the conversion of these Notes on or before December 31, 2022. However, the Company obtained a waiver of this requirement through December 31, 2023 from all holders of the Notes and amended its Articles of Incorporation to increase its number of authorized shares of common stock from 800,000,000 to 2,500,000,000.

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, 2022, and 2021, the Seller Notes had outstanding accrued interest of $1.5 million and $761 thousand, respectively.

The Company evaluated embedded conversion features within the convertible promissory note and determined that the conversion feature does not require to be bifurcated. Upon adoption of ASC 2020-6 effective January 1, 2021, the convertible promissory note is accounted for as a single liability due to the elimination of the beneficial conversion feature accounting model.

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 is currently in default. As of December 31, 2022, and 2021, the note had outstanding accrued interest of $444 thousand and $241 thousand, respectively.

2021 Convertible Promissory Notes Payable – Previously, the Company entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") for the sale by the Company in a private placement (the "2021 Private Placement") of (i) the Company's future advance convertible promissory note in an aggregate principal amount of up to $3.4 million, later amended to $4.2 million and (ii) a warrant to purchase up to an additional 16,666,667 shares of common stock of the Company. The warrants had an exercise price of $0.18 per share and a four-year term. Advances totaled $1.9 million and warrants to purchase 9.3 million shares were outstanding prior to the settlement discussed below.

In addition, the Company issued notes to five institutional investors totaling approximately $0.5 million, which were subject to substantially the same terms and conditions as the Purchase Agreement. Warrants to purchase 2.8 million shares of common stock with an exercise price of $0.18 per share were issued and outstanding prior to the settlement discussed below.

Upon the closing of the Private Placement in August 2022, the 2021 Convertible Promissory Notes Payable were paid and settled in full using proceeds from the Private Placement. The settlement payment included cash totaling $3.9 million, which included accrued interest and penalties, and the issuance of Company shares of common stock totaling 19.4 million shares. The lenders surrendered the outstanding warrants to the Company. The Company recognized a $0.9 million loss on extinguishment of debt during the year ended December 31, 2022.

12. SBA Loans

In February 2021, the Company received proceeds from a U.S. Small Business Administration (SBA) loan in the amount of $1.0 million pursuant to the Paycheck Protection Program under the CARES Act. The SBA Loan was evidenced by a promissory note that matured on February 20, 2026, and bears interest of 1% per annum. The SBA loan contained customary events of default relating to, among other things, payment defaults and breaches of representations, warranties and covenants. All or a portion of SBA loan may be fully or partially forgiven by the SBA upon application by the Company not later than June 2022 in accordance with SBA regulations. The Company received approval of the loan forgiveness application and recognized a gain on the extinguishment totaling $1.0 million during the year ended December 31, 2022.

13. 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. 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, 2022			
(in thousands)	Fair value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 1,416	-	-	$ 1,416
Conversion option	2,340	-	-	2,340
Total Fair Value	$ 3,756	$ -	$ -	$ 3,756

(in thousands)	Fair value measurement at December 31, 2021			
	Fair value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 9,614	-	-	$ 9,614
Conversion option	6,255	-	-	6,255
Total Fair Value	$ 15,869	$ -	$ -	$ 15,869

There were no transfers between Level 1, 2, or 3, during the years ended December 31, 2022, and 2021. Both observable and unobservable in puts 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

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

	December 31, 2022	December 31, 2021
Weighted average expected life in years	4.68	4.67
Weighted average volatility	92%	116%
Value of underlying shares	$ 0.005	$ 0.17
Weighted average risk free interest rate	4.00%	1.20%
Expected dividend yield	-	-

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, 2020	48,091	$ 0.18	$ 8,856
Cashless exercise	(11,400)	0.18	(2,030)
Issuance of warrants classified as liabilities	25,926	0.10	2,282
Change in fair value	-		506
Balance December 31, 2021	62,617	$ 0.15	$ 9,614
Warrants exercised	(27,037)	0.09	(3,130)
Issuance of warrants classified as liabilities	1,031,277	0.06	4,873
Change in fair value	-		(9,941)
Balance December 31, 2022	1,066,857	$ 0.06	$ 1,416

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 of the conversion option was valued using the Black-Scholes model as of December 31, 2022, and the binomial pricing model as of December 31, 2021. Significant inputs related to the Level 3 fair value determination are as follows:

	Initial Valuation Assumptions		Year End Valuation Assumptions	
	August 2022 Convertible Notes	November 2022 Convertible Notes	December 31, 2022	December 31, 2021
Conversion price [1]	$ 0.04	$ 0.04	$ 0.04	$ 0.11
Value of underlying shares	$ 0.006	$ 0.005	$ 0.005	$ 0.17
Interest Rate (annual) [2]	3.24%	4.48%	4.64%	0.18%
Volatility (annual) [3]	349%	438%	503%	290%
Time to maturity	1.00	0.73	0.60	0.50

(1) Based on the terms provided in the convertible promissory note agreements to convert to common stock of the Company
(2) Interest rate for U.S. Treasury Bonds, as of each presented period ending date, as published by the U.S. Federal Reserve.
(3) Based on the historical daily volatility of the Company as of each presented period ending date. As of December 31, 2022 the Company applied a discount rate to the historical volatility.

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

(in thousands)	Conversion Liability
Balance December 31, 2020	$ -
Convertible feature	4,139
Change in fair value	2,116
Balance December 31, 2021	$ 6,255
Issuance of Convertible Notes	2,760
Settlement of convertible notes	(218)
Change in fair value	(6,457)
Balance December 31, 2022	$ 2,340

14. Contract Liabilities

The Company has contract liabilities from contracts with customers as follows:

During the years ended December 31, 2022, and 2021, the Company recognized revenue related to these contract liabilities of $253 thousand and $32 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)	2022	2021
Beginning balance	$ 341	$ 69
New service agreements	202	100
Deposit on future equipment purchases	-	204
Revenue recognized	(253)	(32)
Total Contract Liabilities	$ 290	$ 341

15. Common Stock Purchase Warrants

A summary of the warrant activity is as follows:

(in thousands, except per share data)	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
Warrants at December 31, 2020	190,357	$ 0.19	3.43
Issuances	25,926	0.18	
Exercised	(11,400)	0.01	
Forfeited or expired	-	-	
Outstanding at December 31, 2021	204,883	$ 0.20	2.54
Issuances	1,031,276	0.06	
Exercised	(27,943)	0.09	
Forfeited or expired	-	-	
Outstanding at December 31, 2022	1,208,216	$ 0.07	3.55

On February 3, 2021, the Company issued 10,925,000 shares of its commons stock to a third party upon the cashless exercise of 11,400,000 of common stock warrants under the terms of the warrant agreement.

16. 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.

Also in December 2022, the Company's stockholders approved the Company to amend the Company's Articles of Incorporation to affect a reverse stock split of the Company's outstanding common stock at a reverse stock split ratio ranging from any whole number between 1-for-50 and 1-for-100, with the exact ratio to be determined by the board of directors of the Company in its sole discretion. The Company has not yet affected a reverse stock split of its common stock.

17. Concentration of Credit Risk and Limited Suppliers

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

Accounts Receivable:	December 31, 2022	December 31, 2021
Customer A	-	24%
Customer B	-	16%

The Company currently purchases most of its product component materials from single suppliers and the loss of any of these suppliers could result in a disruption in our production. The percentage of purchases from major vendors of the Company that exceeded ten percent of total purchases were as follows:

	Year ended December 31,	
	2022	2021
Purchases:		
Vendor A	19%	50%
Vendor B	-	21%

18. Revenue

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

	Year ended December 31, 2022			Year ended December 31, 2021		
	United States	International	Total	United States	International	Total
Accessory and parts revenue	$ 9,790	$ 72	$ 9,862	$ 7,770	$ 302	$ 8,072
System revenue	5,179	149	5,328	2,766	350	3,116
License fees and other	283	38	321	135	60	195
Product Revenue	$ 15,252	$ 259	$ 15,511	$ 10,671	$ 712	$ 11,383
Rental Income	1,231	-	1,231	1,627	-	1,627
Total Revenue	$ 16,483	$ 259	$ 16,742	$ 12,298	$ 712	$ 13,010

19. Stock-Based Compensation

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"). The Stock Incentive Plan permits 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 stock options granted under the Stock Incentive Plan are generally non-statutory options which generally vest over a period of up to three years and have a ten-year term. The options are granted at an exercise price determined by the board of directors of the Company to be the fair market value of the common stock on the date of the grant. As of December 31, 2022, and 2021, the Stock Incentive Plan reserved a total of 35,000,000 shares of common stock for grant. On December 31, 2022, there were 3,240,615 shares of common stock available for grant under the Stock Incentive Plan.

20. 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 loss before income taxes are as follows:

	Year ended December 31,	
(In thousands)	2022	2021
Domestic	$ (10,279)	$ (27,208)
Foreign	(12)	(23)
Net loss before income taxes	$ (10,291)	$ (27,231)

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, 2022	December 31, 2021
Current:		
Federal	$ -	$ -
State	2	28
Foreign	-	-
Current Tax Provision	$ 2	$ 28
Deferred:		
Federal	$ (5,657)	$ (5,038)
State	753	(869)
Foreign	(1)	4
Change in valuation allowance	4,905	5,903
Deferred Tax Provision	$ -	$ -

As of December 31, 2022, and 2021, 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.

The income tax provision (benefit) amounts differ from the amounts computed by applying the United States Federal statutory income tax rate of 21% for the years ended December 31, 2022, and 2021. Adjustments to determine income tax expense are as follow:

(In thousands)	Years ended December 31,	
	2022	2021
Tax benefit at statutory rate	$ (2,161)	$ (5,718)
Increase (reduction) in income taxes resulting from:		
State incomes tax benefits, net of federal benefit	(473)	(837)
Non-deductible gain on warrant adjustment valuation	(3,270)	417
Change in valuation allowance	4,905	5,903
Registration penalites	67	354
Other	934	(91)
Income Tax Expense	$ 2	$ 28

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

(In thousands)	December 31, 2022	December 31, 2021
Deferred Tax Assets		
Net operating loss carryforwards	$ 38,323	$ 33,238
Net operating loss carryforwards - foreign	24	23
Excess of tax basis over book value of property and equipment	9	14
Excess of tax basis over book value of intangible assets	1,325	1,622
Lease liability	150	96
Stock-based compensation	1,487	1,613
Accrued employee compensation	750	698
Capitalized equity costs	-	49
Capitalized research and development	116	-
Net change in reserve accounts	1,031	898
Gross deferred tax asset	43,215	38,251
Valuation Allowance	(43,070)	(38,165)
Net Deferred Tax Asset	145	86
Deferred Tax Liabilities		
Right-of-use asset	(145)	(86)
Gross deferred tax liability	(145)	(86)
TOTAL	$ -	$ -

On August 16, 2022, the U.S. government enacted the Inflation Reduction Act of 2022 (the “Inflation Reduction Act”) into law. The Inflation Reduction Act imposes an excise tax of 1% on the fair market value of net stock repurchases made after December 31, 2022. The impact of this provision will be dependent on the extent of share repurchases made in future periods. We continue to analyze the impacts of the Inflation Reduction Act; however, it is not expected to have a material impact on our financial statements. Additionally, the Inflation Reduction Act includes a new corporate alternative minimum tax which is not currently applicable to the Company.

The Tax Cuts and Jobs Act (“TCJA”) requires taxpayers to capitalize and amortize research and development (“R&D”) expenditures under section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during 2022 and resulted in capitalized R&D costs of $0.6 million as of December 31, 2022. The Company will amortize these costs for tax purposes over five years for R&D performed in the U.S. and over 15 years for R&D performed outside the U.S. In 2022, all R&D was performed in the U.S.

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, 2022, and 2021.

The Company’s ability to use its net operating loss carryforwards could be limited and subject to annual limitations. Since a full analysis under Section 382 of the Internal Revenue Code has not been performed, the Company may realize a “more than 50% change in ownership” which could limit its ability to use its net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because United States tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take advantage of all or portions of its net operating loss carryforwards for Federal income tax purposes.

The Federal net operating loss carryforwards of approximately $159.7 million from years ending December 31, 2005, through December 31, 2017, will begin to expire in 2025. The Federal net operating loss carryforward for the years ended December 31, 2018, through 2022 of approximately $81.8 million will not expire. The state net operating loss carryforwards of approximately $70.5 million from years ending December 31, 2005, through December 31, 2022, will expire at various dates through 2042. The foreign net operating loss carryforward on December 31, 2022, of $0.1 million will begin to expire in 2024.

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, 2022, and 2021. 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, 2022, and 2021, the Company did not have any amounts recorded for interest and penalties.

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 occurred.

Acquisition Dispute

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 has responded and asserted that the Company is not in breach and that the supplier has breached various agreements. It is too early to determine the outcome of this matter. Any potential impact to the Company cannot be fully determined at this time and there is no guarantee that the dispute will be resolved in a manner beneficial to the Company or at all.

Lease Commitments

As of December 31, 2022, the maturities of the Company's operating and financing leases, which have initial or remaining lease terms more than one year, consist of the following:

(In thousands)	Operating Leases	Finance Leases
Year ended December 31,		
2023	$ 143	$ 128
2024	85	128
2025	82	78
2026	82	-
2027	55	-
Total Lease Payments	447	334

22. Restatement of Previously Issued Interim Condensed Consolidated Financial Statements

The following tables present the impact of the restatement adjustments disclosed in Note 3 – Restatement of Previously Issued Financial Statements, to the previously reported financial information as of and for the periods ended March 31, 2022, June 30, 2022, and September 30, 2022. Restated Statements of Stockholders' Equity are not presented as all impacted items on those statements, Net Income (Loss), Accumulated deficit, and Total stockholders' equity, are presented within the following tables.

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
RESTATED CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
March 31, 2022

(In thousands, except share data)	Previously Reported	Adjustments	Restated
ASSETS			
Current Assets:			
Cash	$ 313	$ -	$ 313
Accounts receivable, net of allowance of $785	1,730	-	1,730
Inventory	1,001	-	1,001
Prepaid expenses and other current assets	365	-	365
Total Current Assets	$ 3,409	$ -	$ 3,409
Property, Equipment, net	315	-	315
Right of use assets, net	259	-	259
Other Intangible Assets, net	5,665	-	5,665
Goodwill	7,260	-	7,260
Other assets	106	-	106
Total Assets	$ 17,014	$ -	$ 17,014
LIABILITIES			
Current Liabilities:			
Senior secured promissory note payable, in default	$ 11,894	$ -	$ 11,894
Convertible promissory notes payable, in default	10,532	-	10,532
Convertible promissory notes, related parties, in default	1,596	-	1,596
Advances on future cash receipts	416	-	416
Accounts payable	6,696	64	6,760
Accrued expenses	4,916	554	5,470
Accrued employee compensation	3,623	-	3,623
Due under factoring agreement	1,231	-	1,231
Warrant liability	8,300	-	8,300
Current portion of SBA loans	226	-	226
Accrued interest	3,072	60	3,132
Accrued interest, related parties	345	-	345
Current portion of lease liabilities	268	-	268
Current portion of contract liabilities	58	-	58
Other	58	-	58
Total Current Liabilities	$ 53,231	$ 678	$ 53,909
Non-current Liabilities			
SBA loans	$ 807	$ -	$ 807
Lease liabilities	34	-	34
Contract liabilities	303	-	303
Deferred tax liability	28	-	28
Total Non-current Liabilities	$ 1,172	$ -	$ 1,172
Total Liabilities	$ 54,403	$ 678	$ 55,081
STOCKHOLDERS' DEFICIT			
Preferred Stock	$ -	$ -	$ -
Common Stock	517	-	517
Additional Paid-in Capital	150,533	-	150,533
Accumulated Deficit	(188,372)	(678)	(189,050)
Accumulated Other Comprehensive Loss	(67)	-	(67)
Total Stockholders' Deficit	$ (37,389)	$ (678)	$ (38,067)
Total Liabilities and Stockholders' Deficit	$ 17,014	$ -	$ 17,014

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

(In thousands except share data)	Three Months Ended March 31, 2022		
	Previously Reported	Adjustments	Restated
Revenues:			
Accessory and parts revenue	$ 2,192	$ -	$ 2,192
Product	645	-	645
Rental Income	343	-	343
License fees and other	15	-	15
Total Revenue	3,195	-	3,195
Cost of Revenues	889	-	889
Gross Margin	$ 2,306	$ -	$ 2,306
Operating Expenses:			
General and administrative	2,141	64	2,205
Selling and marketing	1,715	-	1,715
Research and development	166	-	166
Gain on disposal of assets	(554)	554	-
Depreciation and amortization	176	-	176
Total Operating Expenses	3,644	618	4,262
Operating Loss	$ (1,338)	$ (618)	$ (1,956)
Other Income (Expense):			
Interest expense	(3,076)	(60)	(3,136)
Interest expense, related party	(56)	-	(56)
Change in fair value of derivative liabilities	3,482	-	3,482
Loss on issuance of debt	(3,434)	-	(3,434)
Gain / (loss) on foreign currency exchange	(1)	-	(1)
Other Expense, net	(3,085)	(60)	(3,145)
Net Loss before Income Taxes	$ (4,423)	$ (678)	$ (5,101)
Provision for Income Taxes	-	-	-
Net Loss	$ (4,423)	$ (678)	$ (5,101)
Other Comprehensive Loss			
Foreign currency translation adjustments	-	-	-
Total Comprehensive Loss	$ (4,423)	$ (678)	$ (5,101)
Loss per Share:			
Net loss per share, basic and diluted	$ (0.01)	$ -	$ (0.01)
Weighted average shares outstanding, basic and diluted	525,414,534	-	525,414,534

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

(In thousands)	Three Months Ended March 31, 2022		
	Previously Reported	Adjustment	Restated
Cash Flows - Operating Activities:			
Net loss	$ (4,423)	$ (678)	$ (5,101)
Adjustments to reconcile net loss to net cash used by operating activities			
Amortization of intangibles	176	-	176
Depreciation	15	-	15
Change in fair value of derivative liabilities	(3,482)	-	(3,482)
Loss on issuance of debt	3,434	-	3,434
Amortization of debt issuance costs and original issue discount	889	-	889
Accrued interest	551	60	611
Interest payable, related parties	56	-	56
Changes in operating assets and liabilities			
Accounts receivable - trade	804	-	804
Inventory	39	-	39
Prepaid expenses	(39)	-	(39)
Other assets	43	-	43
Operating leases	-	-	-
Accounts payable	(930)	64	(866)
Accrued expenses	439	554	993
Accrued employee compensation	(549)	-	(549)
Contract liabilities	(155)	-	(155)
Net Cash Used by Operating Activities	(3,132)	-	(3,132)
Cash Flows - Investing Activities			
Disposition of property and equipment	360	-	360
Net Cash Flows Provided by (Used in) Investing Activities	360	-	360
Cash Flows - Financing Activities			
Proceeds from senior promissory notes	2,940	-	2,940
Payments for factoring	(505)	-	(505)
Proceeds from warrant exercises	100	-	100
Payments of principal on finance leases	(65)	-	(65)
Net Cash Flows Provided by Financing Activities	2,470	-	2,470
Effect of Exchange Rates on Cash	(4)	-	(4)
Net Change in Cash During Period	(306)	-	(306)
Cash at Beginning of Period	619	-	619
Cash at End of Period	$ 313	$ -	$ 313
Supplemental Information:			
Cash paid for interest	$ 574	$ -	$ 574
Non-cash Investing and Financing Activities:			
Reclassification of warrant liability due to cashless warrant exercise	$ 2,167	$ -	$ 2,167
Warrants issued in conjunction with senior secured promissory note payable	2,654	-	2,654
Common shares issued in conjunction with senior secured promissory note payable	3,720	-	3,720

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
RESTATED CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
June 30, 2022

(In thousands, except share data)	Previously Reported	Adjustments	Restated
ASSETS			
Current Assets:			
Cash	$ 1,484	$ -	$ 1,484
Accounts receivable, net of allowance for doubtful accounts of $0.8 million, respectively	1,749	-	1,749
Inventory	925	-	925
Prepaid expenses and other current assets	1,181	(781)	400
Total Current Assets	$ 5,339	$ (781)	$ 4,558
Property, Equipment and Other, net	535	-	535
Other Intangible Assets, net	5,489	-	5,489
Goodwill	7,260	-	7,260
Total Assets	$ 18,623	$ (781)	$ 17,842
LIABILITIES			
Current Liabilities:			
Senior secured promissory note payable, in default	$ 12,334	$ -	$ 12,334
Convertible promissory notes payable, in default	6,523	-	6,523
Convertible promissory notes, related parties, in default	1,596	-	1,596
Short-term loans	1,484	-	1,484
Advances on future cash receipts	398	-	398
Accounts payable	7,083	76	7,159
Accrued expenses	5,900	741	6,641
Accrued employee compensation	4,264	-	4,264
Due under factoring agreement	1,792	-	1,792
Warrant liability	5,295	-	5,295
Current portion of SBA loans	272	-	272
Accrued interest	3,600	137	3,737
Accrued interest, related parties	402	-	402
Current portion of lease liabilities	185	-	185
Current portion of contract liabilities	64	-	64
Other	107	-	107
Total Current Liabilities	$ 51,299	$ 954	$ 52,253
Non-current Liabilities			
SBA loans	$ 761	$ -	$ 761
Lease liabilities	40	-	40
Contract liabilities	295	-	295
Deferred tax liability	28	-	28
Total Non-current Liabilities	$ 1,124	$ -	$ 1,124
Total Liabilities	$ 52,423	$ 954	$ 53,377
STOCKHOLDERS' DEFICIT			
Preferred Stock	$ -	$ -	$ -
Common Stock	529	-	529
Additional Paid-in Capital	151,409	-	151,409
Accumulated Deficit	(185,671)	(1,735)	(187,406)
Accumulated Other Comprehensive Loss	(67)		(67)
Total Stockholders' Deficit	$ (33,800)	$ (1,735)	$ (35,535)
Total Liabilities and Stockholders' Deficit	$ 18,623	$ (781)	$ 17,842

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

(In thousands except share data)	Three Months Ended June 30, 2022			Six Months Ended June 30, 2022		
	Previously Reported	Adj.	Restated	Previously Reported	Adj.	Restated
Revenues:						
Accessory and parts revenue	$ 2,663	$ -	$ 2,663	$ 4,854	$ -	$ 4,854
Product	862	-	862	1,507	-	1,507
Rental Income	344	-	344	688	-	688
License fees and other	13	-	13	28	-	28
Total Revenue	3,882	-	3,882	7,077	-	7,077
Cost of Revenues	1,096	-	1,096	1,986	-	1,986
Gross Margin	$ 2,786	$ -	$ 2,786	$ 5,091	$ -	$ 5,091
Operating Expenses:						
General and administrative	2,937	793	3,730	5,078	857	5,935
Selling and marketing	1,672	-	1,672	3,387	-	3,387
Research and development	171	-	171	337	-	337
Gain on disposal of assets	(136)	187	51	(690)	741	51
Depreciation and amortization	210	-	210	386	-	386
Total Operating Expenses	4,854	980	5,834	8,498	1,598	10,096
Operating Loss	$ (2,068)	$ (980)	$ (3,048)	$ (3,407)	$(1,598)	$ (5,005)
Other Income (Expense):						
Interest expense	(2,826)	(77)	(2,903)	(5,903)	(137)	(6,040)
Interest expense, related party	(56)	-	(56)	(112)	-	(112)
Change in fair value of derivative liabilities	7,861	-	7,861	11,343	-	11,343
Loss on issuance of debt	-	-	-	(3,434)	-	(3,434)
Loss on extinguishment of debt	(211)	-	(211)	(211)	-	(211)
Gain / (loss) on foreign currency exchange	2	-	2	2	-	2
Other Income (Expense), net	4,770	(77)	4,693	1,685	(137)	1,548
Net Income (loss) before Income Taxes	$ 2,702	$(1,057)	$ 1,645	$ (1,722)	$(1,735)	$ (3,457)
Provision for Income Taxes	-	-	-	-	-	-
Net Income (loss)	$ 2,702	$(1,057)	$ 1,645	$ (1,722)	$(1,735)	$ (3,457)
Other Comprehensive Income (Loss)						
Foreign currency translation adjustments	-	-	-	-	-	-
Total Comprehensive Income (Loss)	$ 2,702	$(1,057)	$ 1,645	$ (1,722)	$(1,735)	$ (3,457)
Gain (loss) per Share:						
Basic	$ 0.01	$ (0.01)	$ -	$ -	$ (0.01)	$ (0.01)
Diluted	$ -		$ -	$ -	(0.01)	$ (0.01)
Weighted average shares outstanding; Basic and Diluted						
Basic	538,560,051	-	538,560,051	532,589,825	-	532,589,825
Diluted	871,984,091	-	871,984,091	532,589,825	-	532,589,825

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

(In thousands)	Six Months Ended June 30, 2022		
	Previously Reported	Adjustment	Restated
Cash Flows - Operating Activities:			
Net loss	$ (1,722)	$ (1,735)	$ (3,457)
Adjustments to reconcile net loss to net cash used by operating activities			
Amortization of intangibles	352	-	352
Depreciation	94	-	94
Bad debt expense	52	-	52
Income tax expense	-	-	-
Shares issued for service	888	-	888
Loss in extinguishment of debt	211	-	211
Gain on sale of property and equipment, net	(541)	541	-
Change in fair value of derivative liabilities	(11,343)	-	(11,343)
Loss on issuance of debt	3,434	-	3,434
Amortization of debt issuance costs and original issue discount	1,304	-	1,304
Accrued interest	1,078	137	1,215
Interest payable, related parties	112	-	112
Changes in operating assets and liabilities			
Accounts receivable - trade	733	-	733
Inventory	115	-	115
Prepaid expenses	(855)	781	(74)
Other assets	47	-	47
Accounts payable	(562)	76	(486)
Accrued expenses	1,407	200	1,607
Accrued employee compensation	103	-	103
Contract liabilities	(108)	-	(108)
Net Cash Used by Operating Activities	(5,201)	-	(5,201)
Cash Flows - Investing Activities			
Proceeds from sale of property and equipment	948	-	948
Net Cash Flows Used in Investing Activities	948	-	948
Cash Flows - Financing Activities			
Proceeds from senior promissory notes	2,940	-	2,940
Proceeds from short term notes	2,130	-	2,130
Proceeds from factoring	55	-	55
Proceeds from warrant exercises	100	-	100
Payments of principal on finance leases	(121)	-	(121)
Proceeds from related party advances	-	-	-
Net Cash Flows Provided by Financing Activities	5,104	-	5,104
Effect of Exchange Rates on Cash	14	-	14
Net Change in Cash During Period	865	-	865
Cash at Beginning of Period	619	-	619
Cash at End of Period	$ 1,484	$ -	$ 1,484
Supplemental Information:			
Cash paid for interest	$ 2,045	$ -	$ 2,045
Non-cash Investing and Financing Activities:			
Reclassification of warrant liability due to cashless warrant exercise	2,167	-	2,167
Warrants issued in conjunction with senior secured promissory note payable	2,654	-	2,654
Common shares issued in conjunction with senior secured promissory note payable	3,720	-	3,720

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
RESTATED CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
September 30, 2022

(In thousands, except share data)	Previously Reported	Adjustments	Restated
ASSETS			
Cash	$ 1,112	$ -	$ 1,112
Accounts receivable, net of allowance of $0.8 million, respectively	2,403	-	2,403
Inventory	1,413	(551)	862
Prepaid expenses and other current assets	1,935	(781)	1,154
Total Current Assets	$ 6,863	$ (1,332)	$ 5,531
Property and Equipment and Other, net	673	-	673
Other Intangible Assets, net	5,313	-	5,313
Goodwill	7,260	-	7,260
Total Assets	$ 20,109	$ (1,332)	$ 18,777
LIABILITIES			
Current Liabilities:			
Senior secured promissory note payable, in default	$ 12,773	$ -	$ 12,773
Convertible promissory notes payable, in default	13,174	-	13,174
Convertible promissory notes, related parties, in default	5,858	-	5,858
Advances on future cash receipts	194	-	194
Accounts payable	5,055	170	5,225
Accrued expenses	4,100	741	4,841
Accrued employee compensation	3,792	-	3,792
Due under factoring agreement	1,510	-	1,510
Warrant liability	1,196	-	1,196
Accrued interest	3,988	218	4,206
Accrued interest, related parties	546	-	546
Current portion of lease and contract liabilities	249	-	249
Other	30	-	30
Total Current Liabilities	$ 52,465	$ 1,129	$ 53,594
Non-current Liabilities			
SBA loans	$ -	$ -	$ -
Lease liabilities	263	-	263
Contract liabilities	205	-	205
Deferred tax liability	28	-	28
Total Non-current Liabilities	$ 496	$ -	$ 496
Total Liabilities	$ 52,961	$ 1,129	$ 54,090
STOCKHOLDERS' DEFICIT			
Preferred Stock	$ -	$ -	$ -
Common Stock	549	-	549
Additional Paid-in Capital	152,750	-	152,750
Accumulated Deficit	(186,084)	(2,461)	(188,545)
Accumulated Other Comprehensive Loss	(67)	-	(67)
Total Stockholders' Deficit	$ (32,852)	$ (2,461)	$ (35,313)
Total Liabilities and Stockholders' Deficit	$ 20,109	$ (1,332)	$ 18,777

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

(In thousands except share data)	Three Months Ended September 30, 2022			Nine Months Ended September 30, 2022		
	Previously Reported	Adj.	Restated	Previously Reported	Adj.	Restated
Revenues:						
Accessory and parts revenue	$ 3,012	$ -	$ 3,012	$ 7,866	$ -	$ 7,866
Product	902	-	902	2,408	-	2,408
Rental Income	247	-	247	935	-	935
License fees and other	5	-	5	33	-	33
Total Revenue	4,166	-	4,166	11,242	-	11,242
Cost of Revenues	606	551	1,157	2,590	551	3,141
Gross Margin	$ 3,560	$ (551)	$ 3,009	$ 8,652	$ (551)	$ 8,101
Operating Expenses:						
General and administrative	3,404	94	3,498	8,482	951	9,433
Selling and marketing	1,650	-	1,650	5,037	-	5,037
Research and development	157	-	157	494	-	494
Gain on disposal of assets	-	-	-	(690)	741	51
Depreciation and amortization	189	-	189	575	-	575
Total Operating Expenses	5,400	94	5,494	13,898	1,692	15,590
Operating Loss	$ (1,840)	$ (645)	$ (2,485)	$ (5,246)	$ (2,243)	$ (7,489)
Other Income (Expense):						
Interest expense	(3,301)	(81)	(3,382)	(9,203)	(218)	(9,421)
Interest expense, related party	(439)	-	(439)	(551)	-	(551)
Change in fair value of derivative liabilities	5,252	-	5,252	16,597	-	16,597
Loss on issuance of debt	-	-	-	(3,434)	-	(3,434)
Loss on extinguishment of debt	(86)	-	(86)	(297)	-	(297)
Gain / (loss) on foreign currency exchange	1	-	1	(1)	-	(1)
Other Income (Expense), net	1,427	(81)	1,346	3,111	(218)	2,893
Net Loss before Income Taxes	$ (413)	$ (726)	$ (1,139)	$ (2,135)	$ (2,461)	$ (4,596)
Provision for Income Taxes	-	-	-	-	-	-
Net Income (loss)	$ (413)	$ (726)	$ (1,139)	$ (2,135)	$ (2,461)	$ (4,596)
Other Comprehensive Income (Loss)						
Foreign currency translation adjustments	-	-	-	-	-	-
Total Comprehensive Income (Loss)	$ (413)	$ (726)	$ (1,139)	$ (2,135)	$ (2,461)	$ (4,596)
Loss per Share:						
Basic and Diluted	$ (0.00)	$ -	$ (0.00)	$ (0.00)	$ (0.01)	$ (0.01)
Weighted average shares outstanding, basic and diluted	561,069,625	-	561,069,625	542,484,779	-	542,484,779

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

(In thousands)	Nine Months Ended September 30, 2022		
	Previously Reported	Adjustment	Restated
Cash Flows - Operating Activities:			
Net loss	$ (2,135)	$ (2,461)	$ (4,596)
Adjustments to reconcile net loss to net cash used by operating activities			
Depreciation and Amortization	681	-	681
Bad debt expense	62	-	62
Shares issued for service	888	-	888
Loss on extinguishment of debt	297	-	297
Gain on sale of property and equipment, net	(690)	741	51
Change in fair value of derivative liabilities	(16,597)	-	(16,597)
Loss on issuance of debt	3,434	-	3,434
Amortization of debt issuance costs and original issue discount	2,998	-	2,998
Accrued interest	1,618	218	1,836
Interest payable, related parties	168	-	168
Changes in operating assets and liabilities			
Accounts receivable - trade	69	-	69
Inventory	(373)	551	178
Prepaid expenses and other assets	(1,437)	781	(656)
Accounts payable	(1,863)	170	(1,693)
Accrued expenses	271	-	271
Accrued employee compensation	(473)	-	(473)
Contract liabilities	(94)	-	(94)
Net Cash Used by Operating Activities	(13,176)	-	(13,176)
Cash Flows - Investing Activities			
Disposition of property and equipment	1,022	-	1,022
Net Cash Flows Provided by (Used in) Investing Activities	1,022	-	1,022
Cash Flows - Financing Activities			
Proceeds from senior promissory notes	2,940	-	2,940
Proceeds from convertible promissory notes	12,366	-	12,366
Proceeds from short term notes	640	-	640
Payments for factoring	(227)	-	(227)
Proceeds from warrant exercises	100	-	100
Payments of principal on finance leases	(174)	-	(174)
Payments of principal on convertible promissory notes and SBA loans	(2,981)	-	(2,981)
Net Cash Flows Provided by Financing Activities	12,664	-	12,664
Effect of Exchange Rates on Cash	(17)	-	(17)
Net Change in Cash During Period	493	-	493
Cash at Beginning of Period	619	-	619
Cash at End of Period	$ 1,112	$ -	$ 1,112
Supplemental Information:			
Cash paid for interest	$ 3,345	$ -	$ 3,345
Non-cash Investing and Financing Activities:			
Reclassification of warrant liability due to cashless warrant exercise	$ 2,166	$ -	$ 2,166
Settlement of debt and warrants with stock	1,361	-	1,361
Warrants issued in conjunction with senior secured promissory note payable	2,654	-	2,654
Common shares issued in conjunction with senior secured promissory note payable	3,720	-	3,720
Embedded conversion option with issuances of convertible debt	2,309	-	2,309
Working capital balances refinanced into Convertible notes payable	2,273	-	2,273
Warrant issuance in conjunction with convertible debt	1,463	-	1,463

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, 2022. 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, 2022.

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, 2022. 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 of December 31, 2022, the Company identified the following material weaknesses:

1. Expertise and resources to analyze and properly apply U.S. GAAP to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distributing agreements with select vendors.

2. A lack of internal resources to analyze and properly apply U.S. GAAP to accounting for financial instruments included in service agreements with select vendors.

3. The Company has failed to design and implement controls around all accounting and IT processes and procedures and, as such, we believe that all its accounting and IT processes and procedures need to be re-designed and tested for operating effectiveness.

As a result, management concluded that its internal control over reporting was not effective as of December 31, 2022.

Remediation Plan

We are working with an external vendor to properly document our current internal control policies and procedures to provide the framework for increased effectiveness to test internal controls going forward. We are also adding automated and manual controls into and over the Company's ERP system to ensure that order to cash controls are implemented to mitigate the risk in customer creation, pricing, and accuracy of billing.

We are also working with an outside vendor to improve our IT general controls and set up a proper framework for IT general controls to be executed with the objective to remediate the weaknesses regarding internal controls and provide the framework for testing going forward. The Company has worked with their IT service provider to improve the IT controls on the Company's network environment but has not fully remediated the material weakness. IT controls over the ERP system, particularly as it relates to documentation of change controls will also be improved. Also, a review ensures employees do not have access to initiate transactions beyond their normal duties of their role.

In 2022, we hired internal resources with the proper expertise and experience to apply generally accepted accounting principles. With the passage of time and implementation of additional policies, procedures, and controls, we believe the framework for a proper internal control environment will begin to remediate our material weaknesses.

While the above actions and planned actions are subject to ongoing management evaluation and will require validation and testing of the design and operating effectiveness of internal control over a sustained period, we are committed to continuous improvement and will continue to diligently review our internal control over financial reporting. There is no assurance that the measures described above will be sufficient to remediate the identified material weaknesses and significant deficiencies. The material weaknesses and significant deficiencies will not be considered remediated until management completes the design and implementation of the measures described above, until the controls operate for a sufficient period of time, and until management has concluded, through testing, that the controls are effective.

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, 2022, that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting, except as disclosed above.

Item 9B. OTHER INFORMATION

None

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE MANAGEMENT

Below are the names and certain information regarding the Company's executive officers and directors:

Name	Age	Position Held
Kevin A. Richardson, II	54	Director, Chief Executive Officer
Toni Rinow	58	Chief Financial Officer
Lisa Sundstrom	53	Chief Talent Officer
Peter Stegagno	63	Chief Operating Officer
Iulian Cioanta, PhD	60	Chief Science and Technology Officer
Morgan Frank	51	Director, Chairman of the Board
A. Michael Stolarski	52	Director
Jeff Blizzard	54	Director
Ian Miller	47	Director
James Tyler	65	Director

Kevin A. Richardson, II joined the Company as chairman of the board of directors in October of 2009 and joined SANUWAVE, Inc. as chairman of the board of directors in August of 2005. In November 2012, upon the resignation of the Company's former President and Chief Executive Officer, Christopher M. Cashman, Mr. Richardson assumed the role of Acting Chief Executive Officer, in addition to remaining Chairman of the Board, through the hiring of Mr. Chiarelli in February 2013. In April 2014, Mr. Richardson assumed the role of Co-Chief Executive Officer. When Mr. Chiarelli departed the Company in 2014, Mr. Richardson again assumed the role as Acting Chief Executive Officer. In November 2018, Mr. Richardson was appointed as Chief Executive Officer. Mr. Richardson brings to our board of directors a broad array of financial knowledge for healthcare and other industries. Since 2004, Mr. Richardson served as managing partner of Prides Capital LLC, an investment management firm, until its liquidation in September 2015.

Dr. Toni Rinow joined the Company in August 2022. Dr. Toni Rinow is a highly effective CFO with expertise in publicly held and private equity funded companies. Toni serves as an independent board member and audit committee member for a global IT service provider Converge technology (TSX:CTS) with over $3 billion in revenue. Toni develops high-functioning, performance driven teams to advance transformational change. Her global experience spans healthcare, consumer product goods, and technology delivering accelerated growth. She has expertise in investor and public relations, capital markets, ESG and capital expansion through M&A, financial transactions and public listings. She holds a Master of Business Administration and a Masters in Accounting from the McGill University, was appointed a Chemical Engineer from ERASMUS European Higher Institute of Chemistry in Strasbourg, France and holds a PhD in Biophysics and Chemistry from the University of Montreal, Canada. Toni is trained in Artificial Intelligence at MIT.

Lisa E. Sundstrom joined the Company as Controller in October of 2006, and in August of 2015, assumed the responsibilities of Interim Chief Financial Officer. During 2021, she also assumed the role of Chief Talent Officer, which is the role she currently retains. Ms. Sundstrom began her career with a small public accounting firm, Carnevale & Co., P.C., was Senior Accountant at Mitsubishi Consumer Electronics responsible for the close process and was Accounting Manager for the Benefit Services division of ADP and assisted in the documentation of internal controls for Sarbanes-Oxley compliance. Ms. Sundstrom holds a Bachelor of Science in Accounting from the State University of New York at Geneseo.

Peter Stegagno joined the Company as Vice President, Operations in March 2006. Mr. Stegagno brings to the Company significant experience in the medical device market encompassing manufacturing, design and development, quality assurance and international and domestic regulatory affairs. He most recently served as Vice President of Quality and Regulatory Affairs for Elekta, and other medical device companies including Genzyme Biosurgery. Before focusing on the medical field, Mr. Stegagno enjoyed successful career encompassing production roles in the space industry, including avionics guidance systems for military applications and control computers for the space shuttle. Mr. Stegagno graduated from Tufts University with a Bachelor of Science degree in Chemical Engineering.

Iulian Cioanta, PhD joined the Company in June 2007 as Vice President of Research and Development. Dr. Cioanta most recently served as Business Unit Manager with Cordis Endovascular, a Johnson & Johnson company. Prior to that, Dr. Cioanta worked as Director of Development Engineering with Kensey Nash Corporation, Research Manager at ArgoMed Inc. and Project Manager and Scientist with the Institute for the Design of Research Apparatus. Dr. Cioanta also worked in academia at Polytechnic University of Bucharest in Romania, Leicester University in the United Kingdom and Duke University in the United States. Dr. Cioanta received a Master of Science degree in Mechanical Engineering and Technology form the Polytechnic University of Bucharest and he earned his PhD degree in Biomedical Engineering from Duke University in the field of extracorporeal shock wave lithotripsy.

Morgan Frank joined the board as Chairman in August 2022. Mr. Frank is a founder and principal at Manchester Explorer Fund (18 years) and at Manchester Explorer Ltd (Cayman), two life science focused public equity hedge funds specializing in hands-on microcap growth and development companies. He has 30 years of experience in investing, capital markets, corporate strategy, corporate finance, corporate restarts, and intellectual property. Formerly a principal at First Principles Group, a firm focused on corporate restarts and a portfolio manager for technology and venture capital at Hollis capital, a San Francisco Hedge Fund. He also sits on the board of Modular medical (MODD) a development stage company focused on next generation insulin delivery. Mr. Frank has degrees in economics and political science from Brown University.

Jeff Blizard joined the Board as a Director in April 2022. Mr. Blizard is the Senior Director of Sales at AbioMED, where he led sales of Impella in the surgical market bringing it from 16 million to $150 million in 6 years. Mr.Blizard brings a strong knowledge of capital equipment and sales leadership specific to the medical industry. Throughout his career, Mr. Blizard has shown strength in business and market development.

Ian Miller joined the Board as a Director in April 2022. Mr. Miller is the Commercial Vice President of Hoogwegt US where he manages a team of traders generating more than $500 million in annual revenue by purchasing and selling in excess of 250,000 metric tons of commodities which are distributed around the globe. Mr. Miller has a Master of Business Administration from Drake University and brings over 20 years of sales leadership knowledge that will help SANUWAVE develop its non-medical verticals and growth strategies. Throughout his career, Mr. Miller has built a successful track record for business development and strategic implementation that have helped companies grow both their top and bottom lines.

Jim Tyler joined the Board as a Director in April 2021. Mr. Tyler is an advisory partner to Morgan Stanley Expansion Capital. Mr. Tyler brings over 40 years of operations and financial leadership in various healthcare delivery models. Mr. Tyler built a successful track record for operational excellence, specifically in the wound care industry, as COO with National Healing which later became Healogics, the nation's leading provider of advanced wound care.

A. Michael Stolarski joined the Company as a member of the board of directors in April 2016. Mr. Stolarski founded Premier Shockwave, Inc. in October 2008 and has since served as its President & CEO. From 2005 to 2008, Mr. Stolarski was the Vice President of Business Development and, previously, Acting CFO of SANUWAVE, Inc. From 2001 to 2005, he was the President – Orthopedic Division and Vice President of Finance for HealthTronics Surgical Services, Inc. From 1994 to 2001, he was the CFO and Controller of the Lithotripsy Division, Internal Auditor, and Paralegal of Integrated Health Services, Inc. Mr. Stolarski brings to our board an in-depth understanding of the orthopedic and podiatric shock wave market. In addition to being a Certified Public Accountant in the state of Maryland (inactive), he holds a M.S. in Finance from Loyola College, Baltimore a B.S. in Accounting and a B.S. in Finance from the University of Maryland, College Park.

CORPORATE GOVERNANCE AND BOARD MATTERS

The Board of Directors

The Company's current board of directors consists of six members, five of whom have been determined by the board to be "independent" as defined under the rules of the OTC stock market. The board of directors has determined that Mr. Richardson is not independent under the applicable marketplace rules of the OTC stock market. During 2022, the Board held eleven meetings. Each incumbent director attended at least 75% of the aggregate of the total number of meetings of the Board held during the period for which he has been a director and the total number of meetings held by all committees of the Board on which he served during the periods that he or she served.

Board's Leadership Structure

The Company's board of directors elects the Company's chief executive officer and its chairman, and each of these positions may be held by the same person or may be held by two persons. The chairman's primary responsibilities are to manage the board and serve as the primary liaison between the board of directors and the chief executive officer, while the primary responsibility of the chief executive officer is to manage the day-to-day affairs of the Company, considering the policies and directions of the board of directors. Such an arrangement promotes more open and robust communication among the board and provides an efficient decision-making process with proper independent oversight. The Company's board of directors, as of August 2002, has determined that it is currently in the best interest of the Company and its shareholders to separate the roles of chairman of the board and chief executive officer.

The Company believes, however, that there is no single leadership structure that is always the best and most effective in all circumstances. Accordingly, the board of directors retains the authority to later combine these roles if doing so would be in the best interests of the Company and its shareholders.

The Company's board of directors is authorized to have an audit committee, a compensation committee, and a nominating and corporate governance committee, to assist the Company's board of directors in discharging its responsibilities.

Board's Role in Risk Oversight

While the Company's management is responsible for the day-to-day management of risk to the Company, the board of directors has broad oversight responsibility for the Company's risk management programs. The various committees of the board of directors assist the board of directors in fulfilling its oversight responsibilities in certain areas of risk. In particular, the audit committee focuses on financial and enterprise risk exposures, including internal controls, and discusses with management and the Company's independent registered public accountants the Company's policies with respect to risk assessment and risk management. The compensation committee is responsible for considering those risks that may be implicated by the Company's compensation programs and reviews those risks with the Company's board of directors and chief executive officer.

Audit Committee

The audit committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com*. The primary responsibility of the audit committee is to oversee the Company's financial reporting process on behalf of the board of directors. The Audit Committee reviews and discusses with management and the independent registered public accounting firm the annual audited and quarterly financial statements (including the related disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the annual report on Form 10-K and the quarterly reports on Form 10-Q), reviews the integrity of the financial reporting processes, both internal and external, reviews the qualifications, performance, and independence of the registered public accounting firm. Among other things, the audit committee is also responsible for reviewing with management the effectiveness of the Company's internal controls and disclosure controls and procedures. The audit committee is directly responsible for the appointment, compensation, retention, and oversight of the work of the Company's independent auditors, currently Marcum LLP, including the resolution of disagreements, if any, between management and the auditors regarding financial reporting. In addition, the audit committee is responsible for reviewing and approving any related party transaction that is required to be disclosed pursuant to Item 404 of Regulation S-K promulgated under the Exchange Act.

The current members of the Company's audit committee are Ian Miller (Acting Chairperson), A. Michael Stolarski, and Jeff Blizard. Mr. Stolarski, Mr. Miller, and Mr. Blizard are determined to be independent directors, pursuant to the rules of the OTC stock market. Mr. Miller, who is acting as the chair of the committee, has been determined by the board of directors to be an audit committee financial expert as defined pursuant to the rules of the SEC.

Compensation Committee

The current chair of the Company's compensation committee is Jeff Blizard, who is an independent director, pursuant to the rules of the OTC stock market. The other current members of the compensation committee are A. Michael Stolarski, Ian Miller, and Jim Tyler, who are also independent directors pursuant to the rules of the OTC stock market. The primary purpose of the compensation committee is to discharge the responsibilities of the board of directors relating to compensation of the Company's executive officers. Pursuant to the Company's Compensation Committee Charter, the compensation committee is required to consist of at least two independent directors.

The compensation committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com*. Specific responsibilities of the compensation committee include reviewing and recommending approval of compensation of the Company's named executive officers, administering the Company's stock incentive plan, and reviewing and making recommendations to the Company's board of directors with respect to incentive compensation and equity plans.

Nominating and Corporate Governance Committee

The current chair of the Company's nominating and corporate governance committee is Jim Tyler, who is an independent director, pursuant to the rules of the OTC stock market. The other current members of the committee are Ian Miller, A. Michael Stolarski, and Jeff Blizard, who are also independent directors pursuant to the rules of the OTC stock market. Pursuant to the Company's Nominating and Corporate Governance Committee Charter, the nominating and corporate governance committee is required to consist of at least two independent directors.

The nominating and corporate governance committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com.* Specific responsibilities of the nominating and corporate governance committee include identifying and recommending nominees for election to the Company's board of directors; developing and recommending to the board of directors the Company's corporate governance principles; overseeing the evaluation of the board of directors; and reviewing and approving compensation for non-employee members of the board of directors.

Strategy and Finance Committee

The current chair of the Company's strategy and finance committee is A. Michael Stolarski. The other current members of the committee are James Tyler and Ian Miller. The strategy and finance committee operates under a written charter adopted by the board of directors which is available on the Company's website at *www.sanuwave.com*. Specific responsibilities of the strategy and finance committee include identifying financial strategies to improve the Company's balance sheet position and shareholder value.

Stockholder Communications with the Board of Directors

The board of directors has implemented a process for stockholders to send communications to the board of directors. Stockholders who wish to communicate directly with the board of directors or any director should deliver any such communications in writing to the Secretary of the Company. The Secretary will compile any communications they receive from stockholders and deliver them periodically to the board of directors or the specific directors requested. The Secretary of the Company will not screen or edit such communications but will deliver them in the form received from the stockholder.

Code of Conduct and Ethics

It is the Company's policy to conduct its affairs in accordance with all applicable laws, rules and regulations of the jurisdictions in which it does business. The Company has adopted a code of business conduct and ethics with policies and procedures that apply to all associates (all employees are encompassed by this term, including associates who are officers) and directors, including the chief executive officer, chief financial officer, controller, and persons performing similar functions.

The Company has made the code of business conduct and ethics available on its website at www.sanuwave.com. If any substantive amendments to the code of business conduct and ethics are made or any waivers are granted, including any implicit waiver, the Company will disclose the nature of such amendment or waiver on its website or in a report on Current Report on Form 8-K.

No Family Relationships Among Directors and Officers

There are no family relationships between any director or executive officer of the Company and any other director or executive officer of the Company.

Limitation of Directors Liability and Indemnification

The Nevada Revised Statutes authorize corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Nevada law.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act of 1933, as amended. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is one of our officers or directors, is involved in a legal proceeding of any nature.

There is no pending litigation or proceeding involving any of our directors, officers, employees, or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

DELINQUENT SECTION 16(a) REPORTS

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of our equity securities which are registered pursuant to Section 12 of the Exchange Act, to file with the SEC initial reports of ownership and reports of changes in ownership of our equity securities.

Except as set forth herein, based solely upon a review of the Forms 3, 4 and 5 (and amendments thereto) filed with the SEC, we have determined that our directors, officers and greater than 10% beneficial owners complied with all applicable Section 16 filing requirements, except that A. Michael Stolarksi and Kevin A. Richardson, II each failed to report two purchases of Notes and Common Stock Purchase Warrants; Ian Miller and James Tyler each failed to report one purchase of Notes and Common Stock Purchase Warrants; Opaleye, L.P. failed to file a Form 3 and failed to report two purchases of Notes and Common Stock Purchase Warrants; and Manchester Management Company, LLC, Manchester Management PR, LLC, Manchester Explorer, L.P., James E. Besser and Morgan C. Frank each failed to timely report one purchase of Notes and Common Stock Purchase Warrants.

Item 11. EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program offered to our executives, and in particular to our named executive officers for 2022, who were:

- Kevin A. Richardson, II, Chief Executive Officer;
- John Schlechtweg, Chief Revenue Officer; and
- Lisa Sundstrom, Chief Talent Officer and former Chief Financial Officer.

Summary Compensation Table

The following table provides certain information concerning compensation earned for services rendered in all capacities by our named executive officers during the fiscal years ended December 31, 2022, and 2021.

Name and Position	Year	Salary (1)	All other compensation (2)	Total
	2022	430,583	175,000	605,583
Kevin A. Richardson, II Chief Executive Officer	2021	350,000	49,310	399,310
John Schlechtweg, Chief Revenue Officer	2022	317,500	90,483	407,983
	2021	-	-	-
Lisa Sundstrom, Chief Talent Officer	2022	208,333	82,735	291,068
	2021	200,000	52,023	252,023

(1) Amounts reflect the following:
(i) the salary guaranteed by Mr. Richardson's employment agreement with the Company and
(ii) an aggregate amount of $60,000 for fees earned or paid in cash for Mr. Richardson's service as a director in fiscal 2022.

(2) Includes bonus, health, dental, life and disability insurance premiums and 401(k) matching contributions.

2022 Named Executive Officer Compensation Plan

Base salary

Our salaries reflect the responsibilities of each Named Executive Officer (NEO) and the competitive market for comparable professionals in our industry. Base salaries and benefits packages are fixed components of our NEO's compensation and do not vary with Company performance.

Short term Cash Incentives

The performance-based compensation plan reflects our pay-for-performance philosophy and directly ties short-term incentives to short-term business performance. These awards are linked to specific annual financial goals and key business initiatives for the overall Company. Annual employee bonus incentives are paid to reward achievement of critical short-term operating, financial, and strategic goals. The annual employee bonus is calculated based on a percentage of the each NEO's salary, 50% is paid on individual performance goals, as assigned by leadership and the Board of Directors, and the remainder is paid based on Company performance measures.

Stock Incentive Plan

On October 24, 2006, SANUWAVE, Inc.'s board of directors adopted the 2006 Stock Incentive Plan of SANUWAVE, Inc. (the "2006 Plan"). 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 (previously defined as the "Stock Incentive Plan"). The Stock Incentive Plan permits 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 stock options granted under the Stock Incentive Plan are non-statutory options which vest over a period of up to three years and have a maximum ten-year term. The options are granted at an exercise price equal to the fair market value of the common stock on the date of the grant.

The terms of the options granted under the Stock Incentive Plan expire as determined by individual option agreements (or on the tenth anniversary of the grant date), unless terminated earlier, on the first to occur of the following: (1) the date on which the participant's service with the Company is terminated by the Company for cause; (2) 60 days after the participant's death; or (3) 60 days after the termination of the participant's service with the Company for any reason other than cause or the participant's death; provided that, if during any part of such 60 day period the option is not exercisable solely because of specified securities law restrictions, the option will not expire until the earlier of the expiration date or until it has been exercisable for an aggregate period of 60 days after the termination of the participant's service with the Company. The options vest as provided for in each option agreement and the exercise prices for the options are determined by the board of directors at the time the option is granted, provided that the exercise price shall in no event be less than the fair market value per share of the Company's common stock on the grant date. In the event of any change in the common stock underlying the options, by reason of any merger or exchange of shares of common stock, the board of directors shall make such substitution or adjustment as it deems to be equitable to (1) the class and number of shares underlying such option, (2) the exercise price applicable to such option, or (3) any other affected terms of such option.

In the event of a change of control, unless specifically modified by an individual option agreement: (1) all options outstanding as of the date of such change of control will become fully vested; and (2) notwithstanding (1) above, in the event of a merger or share exchange, the board of directors may, in its sole discretion, determine that any or all options granted pursuant to the Stock Incentive Plan will not vest on an accelerated basis if the board of directors, the surviving corporation or the acquiring corporation, as the case may be, has taken such action that in the opinion of the board of directors is equitable or appropriate to protect the rights and interests of the participants under the Stock Incentive Plan.

No equity awards were issued during the year ended December 31, 2022, and 2021.

Outstanding Equity Awards at 2022 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2022:

Name	Number of securities underlying unexercised options exercisable	Number of securities underlying options unexercisable	Equity incentive plan awards number of securities underlying unexercised unearned options	Exercise price ($)	Expiration Date
Kevin A. Richardson, Chief Executive Officer	115,000	-	-	$ 0.35	2/21/2023
	452,381	-	-	$ 0.11	10/1/2025
	297,619	-	-	$ 0.06	10/1/2025
	700,000	-	-	$ 0.04	6/16/2026
	594,300	-	-	$ 0.18	11/9/2026
	900,000	-	-	$ 0.11	6/14/2027
	1,100,000	-	-	$ 0.21	9/20/2028
	50,000	-	-	$ 0.15	8/26/2029
Lisa E. Sundstrom, Chief Talent Officer	65,000	-	-	$ 0.35	2/21/2023
	25,000	-	-	$ 0.55	5/7/2024
	301,587	-	-	$ 0.11	10/1/2025
	198,413	-	-	$ 0.06	10/1/2025
	500,000	-	-	$ 0.04	6/16/2026
	424,500	-	-	$ 0.18	11/9/2026
	60,000	-	-	$ 0.11	6/14/2027
	750,000	-	-	$ 0.21	9/20/2028
	50,000	-	-	$ 0.15	8/26/2029

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Director Compensation Table for Fiscal Year 2022

The Company provides a base retainer for each director with higher base retainers for service by the Board Chair. The Company provides an additional retainer for committee leadership of the Audit Committee, Compensation Committee, and Strategy and Finance Committee. The Compensation Committee believes the structure aligns compensation according to the level of service contributions by each director.

Director	Fee Earned or paid in cash (in thousands)
Morgan Frank	$ 43
A. Michael Stolarski	$ 70
Jeff Blizzard	$ 63
Ian Miller	$ 63
James Tyler	$ 63

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

The following table sets forth certain information, as of March 15, 2023, with respect to the beneficial ownership of the Company's outstanding common stock by (i) any holder of more than five percent, (ii) each of the Company's named executive officers and directors, and (iii) the Company's directors and executive officers as a group.

Name of Beneficial Owner [1]	Number of Share Beneficially Owned	Percent of Shares Outstanding [2]
Kevin A. Richardson, II [3]	36,531,263	1.7%
Lisa Sundstrom	2,914,500	0.1%
John Schlechtweg	4,016,797	0.2%
Morgan Frank[4]	20,822,917	1.0%
A. Michael Stolarski	127,778,334	6.1%
James Tyler	3,478,125	0.2%
Ian Miller	12,351,696	0.6%
Opaleye LP[5]	207,514,881	9.8%
Manchester Management PR, LLC		
Manchester Management Company, LLC		
Manchester Explorer, L.P.		
James E Besser	233,814,813	11 %
All Directors and Executives as a group (10 persons)	216,496,414	10.2%

(1) Unless otherwise noted, each beneficial owner has the same address as the Company. Jeff Blizzard does not hold any stock in the Company.
(2) Applicable percentage ownership is based on 548,737,651 shares of common stock outstanding as of March 15, 2023. "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and includes options, warrants and convertible promissory notes, that are exercisable within 60 days of March 15, 2023. Unless otherwise indicated, all the listed persons have sole voting and investment power over the shares listed opposite their names. Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 of the Exchange Act.
(3) In addition, this amount includes 4,876,409 shares of common stock owned directly by Prides Capital Fund I, L.P. Prides Capital Partners LLC is the general partner of Prides Capital Fund I, L.P. and Mr. Richardson is the controlling shareholder of Prides Capital Partners LLC; therefore, under certain provisions of the Exchange Act, he may be deemed to be the beneficial owner of such securities. Mr. Richardson has also been deputized by Prides Capital Partners LLC to serve on the board of directors of the Company. Mr. Richardson disclaims beneficial ownership of all such securities except to the extent of any indirect pecuniary interest (within the meaning of Rule 16a-1 of the Exchange Act) therein.

(4) Manchester Management PR, LLC ("**Manchester**") and Manchester Management Company, LLC ("**GP**") may be deemed to be the owner of 39,085,646 shares of Common Stock. Manchester and GP have the sole power to vote or direct the vote of 0 shares of Common Stock, have the shared power to vote or direct the vote of 39,085,646 shares of Common Stock, have the sole power to dispose or direct the disposition of 0 shares of Common Stock, and have the shared power to dispose or direct the disposition of 39,085,646 shares of Common Stock.

Manchester Explorer, L.P. ("**Explorer**") may be deemed to be the beneficial owner of 36,585,646 shares of Common Stock. Explorer has the sole power to vote or direct the vote of 0 shares of Common Stock, has the shared power to vote or direct the vote of 36,585,646 shares of Common Stock, has the sole power to dispose or direct the disposition of 0 shares of Common Stock, and has the shared power to dispose or direct the disposition of 36,585,646 shares of Common Stock.

Mr. Besser has the sole power to vote or direct the vote of 2,250,000 shares of Common Stock, has the shared power to vote or direct the vote of 39,085,646 shares of Common Stock and 193,229,167 shares for warrants and convertible debt. Mr. Besser has the sole power to dispose or direct the disposition of 2,250,000 shares of Common Stock and has the shared power to dispose or direct the disposition of 39,085,646 shares of Common Stock and 193,229,167 shares for warrants and convertible debt.

Mr. Frank has the sole power to vote or direct the vote for 1,500,000 shares of Common Stock and 19,322,917 warrants and debt convertible to Common Stock. Mr. Frank has the shared power to vote or direct the vote of 36,585,646 shares of Common Stock, has the sole power to dispose or direct the disposition of 1,500,000 shares of Common Stock and 19,322,917 warrants and debt convertible to Common Stock. Mr. Frank has the shared power to dispose or direct the disposition of 36,585,646 shares of Common Stock and 193,229,167 shares for warrants and convertible debt.

Mr. Besser is the managing member of Manchester and GP and Mr. Frank serves as a portfolio manager and as a consultant for Explorer. Manchester is the investment manager of Explorer and GP is the general partner of Explorer. The principal business address for each of Manchester, GP, Explorer and Messrs. Besser and Frank is 2 Calle Candina, #1701, San Juan, Puerto Rico, 00907.

(5) Opaleye Management Inc. (the "**Opaleye**") serves as investment manager to Opaleye, L.P. and as a portfolio manager for a separate managed account (the "**Managed Account**") and may be deemed to indirectly beneficially own securities owned by the Managed Account. Opaleye disclaims beneficial ownership of the shares held by the Managed Account. Mr. James Silverman is the President of Opaleye. The address of Opaleye is One Boston Place, 26th Floor, Boston, MA 02108.

Securities Authorized for Issuance Under Equity Compensation Plans

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (c)
Equity compensation plans approved by security holders	-	$ -	-
Equity compensation plans not approved by security holders	21,246,085	0.28	3,240,615
Total	21,246,085	$ 0.28	3,240,615

Stock Incentive Plans

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"). The Stock Incentive Plan permits 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 currently 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 stock options granted under the Stock Incentive Plan are generally non-statutory options which vest over a period of up to three years and have a ten-year term. The options are granted at an exercise price equal to the fair market value of the common stock on the date of the grant which is approved by the board of directors of the Company.

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

Director Independence

Our board of directors has determined that Morgan Frank, Jeff Blizard, Ian Miller, Jim Tyler and A. Michael Stolarski qualify as independent directors based on the OTC stock market definition of "independent director." Our board of directors has determined that our other director, Kevin A. Richardson II, does not qualify as an independent director based on the OTC stock market definition of "independent director." There are no family relationships among any of the directors or executive officers of the Company.

Related Party Transactions

On August 6, 2020, the Company issued to A. Michael Stolarski a convertible promissory note in the principal amount of $223 thousand. The Stolarski Note has a maturity date of August 6, 2021, and accrues interest at a rate equal to 12.0% per annum. On October 27, 2021, the Company issued to Mr. Stolarski a promissory note in the principal amount of $150 thousand ("Stolarski Note #2"). The Stolarski Note #2 matures on June 30, 2022, and accrues interest at a rate equal to 15.0% per annum. On April 1, 2022, the Company entered into a Reverse Repurchase Agreement with a related party, A. Michael Stolarski, also a shareholder and member of the Company's board of directors, in the amount of $250 thousand. In August 2022, all notes including interest were refinanced into the August 2022 convertible promissory notes totaling $730 thousand.

In March 2021, PSWC a company owned by Mr.Stolarski paid the Company $125 thousand as a deposit for future purchase of new medical equipment. Also, in July 2021, the Company purchased unused Pace equipment and applicator inventory from PSWC for $127 thousand. As of December 31, 2021, $127 thousand is included in accounts payable on the consolidated balance sheets related to this transaction.

In August 2022 and November 2022, the Company entered into Purchase Agreements for the sale of Notes and Common Stock Purchase Warrants in an aggregate principal amount of $16.2 million in August and $4.0 million in November. In these transactions, James Besser, a beneficial owner of more than five percent of the Company's common stock; Morgan C. Frank, Chairman of the Board and a beneficial owner of more than five percent of the Company's common stock; John F. Nemelka, a former director, Kevin A. Richardson, II, former Chairman of the Board and current Chief Executive Officer of the Company; A. Michael Stolarski; Manchester Explorer, L.P., a beneficial owner of more than five percent of the Company's common stock; and Opaleye, L.P., a beneficial owner of more than five percent of the Company's common stock, purchased Notes, which were accompanied by Common Stock Purchase Warrants, with an aggregate principal amount of $400,000, $250,000, 233,847, $261,780, $1,434,966, $2,500,000 and $2,900,000, respectively. Messrs. Besser and Frank share voting and dispositive power with respect to the securities acquired by Manchester Explorer, L.P. The Notes issued to each of Messrs. Richardson and Stolarski included $90,000 in principal amount for which the consideration was accrued and unpaid director fees. Additional information regarding the Notes and accompanying Common Stock Purchase Warrants issued in August 2022 and November 2022 is disclosed in Note 11 to the consolidated financial statements in Part II, Item 8. "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table summarizes the fees that we have paid or accrued for audit and other services provided by our prior principal independent registered public accounting firm, Marcum LLP:

(In thousands)	For the Year Ended December 31,	
Fee Category	2022	2021
Audit fees	$ 504	$ 402
Tax fees	-	7
Audit related fees	-	-
All other fees	-	-
Total Fees	$ 504	$ 409

For purposes of the preceding table:

- *Audit fees* consist of fees for the annual audit of our consolidated financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with statutory and regulatory filings and consents related to capital markets transactions and engagements for those fiscal years.
- *Tax fees* consist of fees for tax compliance, tax advice and tax planning services for those fiscal years.
- *Audit related fees* consist of fees for assurance and related services that are reasonably related to the performance of the audit or review.
- *All other fees* consist of fees for all other products and services.

The audit committee must pre-approve all audits and permitted non-audit services to be provided by our principal independent registered public accounting firm unless an exception to such pre-approval exists under the Exchange Act or the rules of the SEC. Each year, the board of directors approves the retention of the independent auditor to audit our consolidated financial statements, including the associated fee. At this time, the audit committee evaluates and approves other known potential engagements of the independent auditor, including the scope of audit-related services, tax services and other services proposed to be performed and the proposed fees, and approves or rejects each service, taking into account whether the services are permissible under applicable law and the possible impact of each non-audit service on the independent auditor's independence from management.

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.

3. Exhibits

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 September 25, 2009, by and between Rub Music Enterprises, Inc., RME Delaware Merger Sub, Inc. and SANUWAVE, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Form 10-SB filed with the SEC on December 18, 2007).
3.2	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Appendix A to the Definitive Schedule 14C filed with the SEC on October 16, 2009).
3.3	Certificate of Amendment to the Articles of Incorporation (Incorporated by reference to Exhibit A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).
3.4	Bylaws (Incorporated by reference to Exhibit 3.02 to the Form 10-SB filed with the SEC on December 18, 2007).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company dated March 14, 2014 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on March 18, 2014).
3.6	Certificate of Amendment to the Articles of Incorporation, dated September 8, 2015 (Incorporated by reference to Exhibit 3.6 to the Form 10-K filed with the SEC on March 30, 2016).
3.7	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 C Convertible Preferred Stock of the Company dated January 31, 2020 (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on February 6, 2020).
3.10	Certificate of Designation of Series D Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on May 20, 2020).

3.11	Certificate of Amendment of the Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on January 5, 2021).
3.12	Certificate of Amendment of the Articles of Incorporation, dated January 31, 2023 (Incorporated by reference to Exhibit 3.12 to the Form S-1/A filed with the SEC on January 31, 2023).
4.1	Form of Class A Warrant Agreement (Incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the SEC on September 30, 2009).
4.2	Form of Class B Warrant Agreement (Incorporated by reference to Exhibit 4.2 to the Form 8-K filed with the SEC on September 30, 2009).
4.3	Form of Class D Warrant Agreement (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on October 14, 2010).
4.4	Form of Class E Warrant Agreement (Incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the SEC on April 7, 2011).
4.5	Form of Series A Warrant (Incorporated by reference to the Exhibit 4.1 to the Form 8-K filed with the SEC on March 18, 2014).
4.6	Form of Series B Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.7	Form of 18% Senior Secured Convertible Promissory Note issued by the Company to select accredited investors (Incorporated by reference to Form 8-K filed with the SEC on February 27, 2013).
4.8	Form of Convertible Promissory Note between the Company and accredited investors party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.9	Amendment No. 1 to the Convertible Note Agreement between the Company and accredited investors party thereto (Incorporated by reference to the Form 8-K filed with the SEC on March 18, 2014).
4.10	Class K Warrant Agreement by and between the Company and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to the Form 8-K filed with the SEC on June 18, 2015).
4.11	Amendment No. 1 to Class K Warrant Agreement by and between the Company and HealthTronics, Inc., dated June 28, 2016 (Incorporated by reference to the Form 10-Q filed with the SEC on August 15, 2016).
4.12	Form of Class L Warrant Common Stock Purchase Warrant (Incorporated by reference to the Form 8-K filed with the SEC on March 17, 2016).
4.13	Second Form of Class L Warrant Common Stock Purchase Warrant (Incorporated by reference to the Form 8-K filed with the SEC on August 24, 2016).
4.14	Registration Rights Agreement dated January 13, 2016 among the Company and the investors listed therein (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
4.15	Class K Warrant Agreement dated as of August 3, 2017, between the Company and HealthTronics, Inc. (Incorporated by reference to Form 8-K filed with the SEC on August 4, 2017).
4.16	Form of Class N Warrant. (Incorporated by reference to Form 8-K filed with the SEC on November 9, 2017).
4.17	Letter to Series A Warrantholders, Class N Warrantholders and Class L Warrantholders, dated January 29, 2019. (Incorporated by reference to Form 8-K filed with the SEC on January 25, 2019).
4.18	Form of Class O Warrant. (Incorporated by reference to Form 8-K filed with the SEC on March 15, 2019).
4.19	Letter to Class N Warrantholders and Class O Warrantholders, dated March 14, 2019. (Incorporated by Reference to Form 8-K filed with the SEC on March 15, 2019).
4.20	Letter to Class N Warrant Holders, dated June 5, 2019 (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on June 7, 2019).

4.21	Letter to Class O Warrant Holders, dated June 5, 2019 (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on June 7, 2019).
4.22*	Description of Registrant's Common Stock. (Incorporated by reference to the Company's Form 10-K for the year ended December 31, 2021).
4.23	Form of Class E Warrant (Incorporated by reference to the Form 8-K filed with the SEC on August 12, 2020).
4.24	Form of Secured Promissory Note issued to NH Expansion Credit Fund Holdings LP, dated August 6, 2020 (Incorporated by reference to the Form 8-K filed with the SEC on August 12, 2020).
4.25	Warrant issued to NH Expansion Credit Fund Holdings LP, dated August 6, 2020 (Incorporated by reference to the Form 8-K filed with the SEC on August 12, 2020).
4.26	Warrant issued to HealthTronics, Inc., dated August 6, 2020 (Incorporated by reference to the Form 8-K filed with the SEC on August 12, 2020).
4.27	Form of Future Advance Convertible Promissory Note issued to certain purchasers, dated August 5, 2022 (Incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the SEC on August 8, 2022).
4.28	Form of Common Stock Purchase Warrant issued to certain purchasers, dated August 5, 2022 (Incorporated by reference to Exhibit 4.2 to the Form 8-K filed with the SEC on August 8, 2022).
4.29	Form of Future Advance Convertible Promissory Note issued to certain purchasers, dated November 14, 2022 (Incorporated by reference to Exhibit 4.3 to the Form S-1/A filed with the SEC on January 31, 2023).
4.30	Form of Common Stock Purchase Warrant issued to certain purchasers, dated November 14, 2022 (Incorporated by reference to Exhibit 4.4 to the Form S-1/A filed with the SEC on January 31, 2023).
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	Form of Securities Purchase Agreement, by and among the Company and the accredited investors party thereto, dated March 17, 2014 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on March 18, 2014).
10.3	Form of Registration Rights Agreement, by and among the Company and the holders party thereto, dated March 17, 2014 (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on March 18, 2014).
10.4	Company and the accredited investors a party thereto (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on March 18, 2014).
10.5	Amendment to certain Promissory Notes that were dated August 1, 2005, by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on June 18, 2015.)
10.6	Security Agreement, by and between the Company and HealthTronics, Inc., dated June 15, 2015 (Incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the SEC on June 18, 2015).
10.7	Exchange Agreement dated January 13, 2016 among the Company and the investors listed therein (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on January 19, 2016).
10.8	Escrow Deposit Agreement dated January 25, 2016 among the Company, Newport Coast Securities, Inc. and Signature Bank (Incorporated by reference to Exhibit 10.10 to the Form S-1/A filed with the SEC on February 3, 2016).
10.9	Second Amendment to Certain Promissory Notes entered into as of June 28, 2016 by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to Exhibit 10.1 to the Form 10-Q filed with the SEC on August 15, 2016).

10.10	Form of Securities Purchase Agreement, by and among the Company and the accredited investors a party thereto, dated March 11, 2016 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on March 17, 2016).
10.11	Form of Securities Purchase Agreement, by and between the Company and the accredited investors a party thereto, dated August 24, 2016 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on J August 25, 2016).
10.12	Form of Registration Rights Agreement, by and between the Company and the holders a party thereto, dated August 24, 2016 (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on August 25, 2016).
10.13	Third Amendment to promissory notes entered into as of August 3, 2017 by and among the Company, SANUWAVE, Inc. and HealthTronics, Inc. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on August 4, 2017).
10.14#	Distribuidora Hospitalar LTDA effective as of September 25, 2017 (Incorporated by reference to Exhibit 10.2 to the Form 10-Q filed with the SEC on November 15, 2017).
10.15	Form of 10% Convertible Promissory Note, by and among the Company and the accredited investors a party thereto. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on November 9, 2017).
10.16	Form of Registration Rights Agreement, by and among the Company and the accredited investors a party thereto (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on November 9, 2017).
10.17#	Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs of PACE Systems and Equipment among the Company, and Premier Shockwave Wound Care, Inc. and Premier Shockwave, Inc. dated as of February 13, 2018. (Incorporated by reference to Exhibit 10.17 to the Form 10-K filed with the SEC on March 29, 2018).
10.18	Agreement, dated June 14, 2018, by and among the Company and Johnfk Medical Inc. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on June 29, 2018).
10.19	Joint Venture Agreement, dated September 21, 2018, by and among the Company, Johnfk Medical Inc. and Holistic Health Institute Pte. Ltd. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on September 27, 2018).
10.20	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).
10.21∞	Offer Letter, dated as of November 30, 2018, by and between SANUWAVE Health, Inc. and Kevin Richardson. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on December 4, 2018).
10.22∞	Offer Letter, dated as of April 15, 2018, by and between SANUWAVE Health, Inc., and Shri Parikh. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on June 7, 2018).
10.23	Deed of Termination of Joint Venture Agreement, dated June 4, 2019, by and among the Company, Johnfk Medical Inc. and Holistic Wellness Alliance Pte. Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 17, 2019).
10.24	Common Stock Purchase Agreement, by and among the Company and the accredited investors party thereto, dated December 11, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on December 27, 2019).
10.25	Registration Rights Agreement, by and among the Company and the accredited investors party thereto, dated December 11, 2019 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on December 27, 2019).

10.26*β	Joint Venture Agreement, dated December 13, 2019, by and among the Company, Universus Global Advisors LLC, Versani Health Consulting Consultoria Em Gestao De Negocios Eireli, and the IDIC Group as set forth therein (Incorporated by reference to the Form 8-K filed with the SEC on January 28, 2020).
10.27	Separation Agreement and General Release, dated as of May 14, 2020 by and between SANUWAVE Health, Inc. and Shri P. Parikh (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on May 18, 2020).
10.28	Series D Preferred Stock Purchase Agreement, by and among the Company and the accredited investors party thereto, dated May 14, 2020 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on May 20, 2020).
10.29	Promissory Note by and between SANUWAVE Health, Inc. and Truist Bank, dated May 28, 2020 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on June 1, 2020).
10.30	Securities Purchase Agreement, dated as of June 5, 2020, by and between the Company and LGH Investments, LLC (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on June 11, 2020).
10.31	Convertible Promissory Note, dated as of June 5, 2020, issued by the Company to LGH Investments, LLC (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on June 11, 2020).
10.32	Common Stock Purchase Warrant, dated as of June 5, 2020, issued by the Company to LGH Investments, LLC (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on June 11, 2020).
10.33	Asset Purchase Agreement by and between the Company and Celularity Inc., dated August 6, 2020 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on August 12, 2020).
10.34	License and Marketing Agreement by and between the Company and Celularity Inc., dated August 6, 2020 (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on August 12, 2020).
10.35	Convertible Promissory Note issued to Celularity Inc., dated August 6, 2020 (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on August 12, 2020).
10.36	Form of Securities Purchase Agreement by and among the Company and the accredited investors a party thereto, dated August 6, 2020 (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on August 12, 2020).
10.37	Note and Warrant Purchase and Security Agreement by and among the Company, the noteholder party thereto and NH Expansion Credit Fund Holdings LP, as agent, dated August 6, 2020 (Incorporated by reference to Exhibit 10.5 to the Form 8-K filed with the SEC on August 12, 2020).
10.38	Letter Agreement by and between the Company and HealthTronics, Inc., dated August 6, 2020 (Incorporated by reference to Exhibit 10.6 to the Form 8-K filed with the SEC on August 12, 2020).
10.39	Convertible Promissory Note issued to HealthTronics, Inc., dated August 6, 2020 (Incorporated by reference to Exhibit 10.7 to the Form 8-K filed with the SEC on August 12, 2020).
10.40	Securities Purchase Agreement by and between the Company and HealthTronics, Inc., dated August 6, 2020 (Incorporated by reference to Exhibit 10.8 to the Form 8-K filed with the SEC on August 12, 2020).
10.41	Convertible Promissory Note issued to A. Michael Stolarski, dated August 6, 2020 (Incorporated by reference to Exhibit 10.9 to the Form 8-K filed with the SEC on August 12, 2020).
10.42	Securities Purchase agreement by and between the Company and Leviston Resources, LLC, dated April 20, 2021 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on April 27, 2021).
10.43	Subordination Agreement by and among the Company, Leviston Resources, LLC and NH Expansion Credit Fund Holdings LP, dated April 20, 2021 (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on April 27, 2021).
10.44	Registration Rights Agreement by and between the Company and Leviston Resources, LLC, dated April 20, 2021 (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on April 27, 2021).

10.45	Form of Securities Purchase Agreement Entered into September 3, 2021 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on September 13, 2021).
10.46	Form of Subordination Agreement Entered into September 3, 2021 (Incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on September 13, 2021).
10.47	Form of Registration Rights Agreement Entered into September 3, 2021 (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on September 13, 2021).
10.48	Form of Security Agreement (Incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on September 13, 2021).
10.49	Future Receivables Agreement by and between GCF Resources, LLC and SANUWAVE Health, Inc. dated September 27, 2021 (Incorporated by reference to Exhibit 10.3 filed with the Form 10-Q for the quarter ended March 31, 2021 filed with the SEC on December 13, 2021).
10.50	Form of Registration Rights Agreement entered into September 27, 2021 (Incorporated by reference to Exhibit 10.6 filed with the Form 10-Q for the quarter ended September 30, 2021).
10.51	Form of Warrant Issued September 27, 2021, and December 22, 2021 (Incorporated by reference to Exhibit 10.7 filed with the Form 10-Q for the quarter ended September 30, 2021).
10.52	Master Equipment and Contracts Purchase Agreement by and between the Company and ABF SANUWAVE, LLC dated February 17, 2022 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on February 24, 2022).
10.53	Second Amendment to the Note and Warrant Purchase and Security Agreement by and between the Company and NH Expansion Credit Fund Holdings L.P., dated February 25, 2022 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on March 2, 2022).
10.54	Form of Warrant Issued September 27, 2021 and December 22, 2021 (Incorporated by reference to Exhibit 10.7 filed with the Form 10-Q for the quarter ended September 30, 2021).
10.55	Form of Refinance Agreement by and between GCF Resources, LLC and SANUWAVE Health, Inc. dated December 22, 2021 (Incorporated by reference to Exhibit 10.55 to the Form 10-K filed with the SEC on May 13, 2022).
10.56	Future Receivables Agreement by and between GCF Resources, LLC and SANUWAVE Health, Inc. dated December 22, 2021 (Incorporated by reference to Exhibit 10.56 to the Form 10-K filed with the SEC on May 13, 2022).
10.57	Form of Security Agreement and Guarantee by and between GCF Resources, LLC and SANUWAVE Health, Inc. dated December 22, 2021 (Incorporated by reference to Exhibit 10.57 to the Form 10-K filed with the SEC on May 13, 2022).
10.58	Master Equipment and Contracts Purchase Agreement by and between the company and ABF Sanuwave, LLC dated February 17, 2022 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on February 24, 2022).
10.59	Second Amendment to the Note and Warrant Purchase and Security Agreement by and between the Company and NH Expansion Credit Fund Holdings L.P., dated February 25, 2022 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on March 2, 2022).
10.60	Form of Advance Agreement by and between the Company and A. Michael Stolarski dated March 31, 2022 (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed with the SEC on May 26, 2022).
10.61	Form of Securities Purchase Agreement, dated August 5, 2022, by and among the Company and the purchasers identified on the signature pages thereto (Incorporated by reference to Exhibit 10.1 the Form 8-K filed with the SEC on August 8, 2022).

10.62	Form of Subordination Agreement, dated August 5, 2022, by and among the Company, NH Expansion Credit Fund Holdings LP and certain creditors (Incorporated by reference to Exhibit 10.2 the Form 8-K filed with the SEC on August 8, 2022).
10.63	Form of Security Agreement, dated August 5, 2022, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on August 8, 2022).
10.64	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).
10.65	Settlement Agreement, dated August 5, 2022, by and between the Company and Leviston Resources LLC (Incorporated by reference to Exhibit 10.5 to the Form 8-K filed with the SEC on August 8, 2022).
10.66	Third Amendment to the Note and Warrant Purchase and Security Agreement by and between the Company and NH Expansion Credit Fund Holdings L.P., dated June 30, 2022 (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on July 7, 2022).
10.67	Securities Purchase Agreement, dated November 14, 2022, by and among the Company and the purchasers identified on the signature pages thereto (Incorporated by reference to Exhibit 10.67 to the Form S-1/A filed with the SEC on January 31, 2023).
10.68	Subordination Agreement, dated November 14, 2022, by and among the Company, NH Expansion Credit Fund Holdings LP and certain creditors (Incorporated by reference to Exhibit 10.68 to the Form S-1/A filed with the SEC on January 31, 2023).
10.69	Security Agreement, dated November 14, 2022, by and among the Company and certain lenders (Incorporated by reference to Exhibit 10.69 to the Form S-1/A filed with the SEC on January 31, 2023).
10.70	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).
10.71∞	Offer Letter, dated April 7, 2022, by and between the Company and Dr. Toni Rinow (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on August 19, 2022).
21.1*	List of subsidiaries
23.1*	Consent of Marcum LLP, independent registered public accountants.
24.1*	Power of Attorney (included on signature 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.
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.

Table of Contents

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 31, 2023

By: */s/ Kevin A. Richardson, II*
Name: Kevin A. Richardson, II
Title: Chief Executive Officer

POWER OF ATTORNEY

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Kevin A. Richardson, II and Toni Rinow, 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/ Kevin A. Richardson, II* Name: Kevin A. Richardson, II	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	March 31, 2023
By: */s/ Toni Rinow* Name: Toni Rinow	Chief Financial Officer (principal financial and accounting officer)	March 31, 2023
By: */s/ Morgan Frank* Name: Morgan Frank	Director	March 31, 2023
By: */s/ A. Michael Stolarski* Name: A. Michael Stolarski	Director	March 31, 2023
By: */s/ Jeff Blizard* Name: Jeff Blizard	Director	March 31, 2023
By: */s/ Ian Miller* Name: Ian Miller	Director	March 31, 2023
By: */s/ Jim Tyler* Name: Jim Tyler	Director	March 31, 2023