FORM 10-K

Annual report pursuant to section 13 and 15(d)

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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, 2021

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.)**
3360 Martin Farm Road, Suite 100 **Suwanee, Georgia**	**30024**
(Address of Principal Executive Offices)	**(Zip Code)**

(770) 419-7525
Registrant's Telephone Number, Including Area Code
Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001

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(b) of the Act:
None

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months YES ☒ NO ☐

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

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. ☒

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% shareholders are affiliates of the registrant), based upon the closing sale price of the registrant's common stock on June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was $81.6 million.

As of May 10, 2022, there were issued and outstanding 517,195,705 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: any expected benefits of the Celularity Inc. asset acquisition and its impact on the Company; the impact of the COVID-19 pandemic on our business, 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 dermaPACE® and our product candidates; 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 affect the level of demand for our products; timing of clinical studies and eventual FDA approval of our products; financial markets; the competitive environment; 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 prior and future 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.

Item 1. BUSINESS

Overview

We are a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. Our initial focus is regenerative medicine utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal, and vascular structures.

Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. On December 28, 2017, the U.S. Food and Drug Administration (the "FDA") granted the Company's request to classify the dermaPACE® System as a Class II device via the *de novo* process. As a result of this decision, the Company was able to immediately market the product for the treatment of diabetic foot ulcers as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. The Company is marketing its dermaPACE® System for treatment usage in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia, Brazil, Mexico, and Asia/Pacific. The Company generates revenue streams from dermaPACE® treatments, product sales, licensing transactions and other activities, and with its recent acquisition of the UltraMIST® assets, SANUWAVE now combines two highly complementary and market-cleared energy transfer technologies used in the dermaPACE® and UltraMIST® Systems and two human tissue biologic products (Biovance® and Interfyl®), creating a platform of scale with an end-to-end product offering in the advanced wound care market.

Our lead product candidate for the global wound care market, dermaPACE®, has received FDA clearance for commercial use to treat diabetic foot ulcers in the United States and the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. We believe we have demonstrated that our patented technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III Premarket Approvals ("PMAs") approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe and Asia.

We are focused on developing our PACE technology to activate healing in:

(1) wound conditions, including diabetic foot ulcers, venous and arterial ulcers, pressure sores, burns and other skin eruption conditions;
(2) orthopedic applications, such as eliminating chronic pain in joints from trauma, arthritis or tendons/ligaments inflammation, 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;
(3) plastic/cosmetic applications such as cellulite smoothing, graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and
(4) cardiac applications for removing plaque due to atherosclerosis improving heart muscle 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 and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

The worldwide spread of the COVID-19 virus resulted in a global slowdown of economic activity which is likely to decrease demand for a broad variety of products, including from our customers. We have experienced a disruption of our supply channels which will continue for an unknown period of time until the global supply chain can return to the pre- disease status. Also, the pandemic may cause 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 and we expect that they will continue to have a negative impact on our sales and our results of operations, the size and duration of which we are currently unable to predict.

Pulsed Acoustic Cellular Expression (PACE) Technology for Regenerative Medicine

Our PACE product candidates, including our lead product candidate, dermaPACE®, deliver high-energy acoustic pressure waves in the shock wave spectrum 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 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 (arteriogenesis), 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 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. We believe that 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.

High-energy, acoustic pressure shock waves are the primary component of our previously developed product, OssaTron, which was approved by the FDA and marketed in the United States for use in chronic plantar fasciitis of the foot in 2000 and for elbow tendonitis in 2003. Previously, acoustic pressure shock waves have been used safely at much higher energy and pulse levels in the lithotripsy procedure (breaking up kidney stones) by urologists for over 25 years and has reached the care status of "golden standard" for the treatment of kidney stones.

We research, design, manufacture, market and service our products worldwide and believe we have already demonstrated that our technology is safe and effective in stimulating healing in chronic musculoskeletal conditions of the foot and the elbow through our United States FDA Class III PMA approved OssaTron device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our orthoPACE, Evotron and OssaTron devices in Europe, Asia and Asia/Pacific.

We believe our experience from our preclinical research and the clinical use of our predecessor legacy devices in Europe and Asia, as well as our OssaTron device in the United States, demonstrates the safety, clinical utility and efficacy of these products. In addition, we have preclinical programs focused on the development and better understanding of treatments specific to our target applications.

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. We believe that our pre-clinical and clinical studies suggest that our PACE technology will be effective in targeted applications. We anticipate 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, we believe 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 Lead Product Candidate

The FDA granted approval of our Investigational Device Exemption (IDE) to conduct two double-blinded, randomized clinical trials utilizing our lead device product for the global wound care market, the dermaPACE® device, in the treatment of diabetic foot ulcers.

The dermaPACE® system was evaluated using two studies under IDE G070103. The studies were designed as prospective, randomized, double-blind, parallel-group, sham-controlled, multi-center 24-week studies at 39 centers. A total of 336 subjects were enrolled and treated with either dermaPACE® plus conventional therapy or conventional therapy (a.k.a. standard of care) alone. Conventional therapy included, but was not limited to, debridement, saline-moistened gauze, and pressure reducing footwear. The objective of the studies was to compare the safety and efficacy of the dermaPACE® device to sham-control application. The prospectively defined primary efficacy endpoint for the dermaPACE® studies was the incidence of complete wound closure at 12 weeks post-initial application of the dermaPACE® system (active or sham). Complete wound closure was defined as skin re-epithelialization without drainage or dressing requirements, confirmed over two consecutive visits within 12-weeks. If the wound was considered closed for the first time at the 12-week visit, then the next visit was used to confirm closure. Investigators continued to follow subjects and evaluate wound closure through 24 weeks.

Between the two studies there were over 336 patients evaluated, with 172 patients treated with dermaPACE® and 164 control group subjects with use of a non-functional device (sham). Both treatment groups received wound care consistent with the standard of care in addition to device application. Study subjects were enrolled using pre-determined inclusion/exclusion criteria in order to obtain a homogenous study population with chronic diabetes and a diabetic foot ulcer that has persisted a minimum of 30 days and its area is between 1cm^2 and 16cm^2, inclusive. Subjects were enrolled at Visit 1 and followed for a run-in period of two weeks. At two weeks (Visit 2 – Day 0), the first treatment was applied (either dermaPACE® or Sham Control application). Applications with either dermaPACE® or Sham Control were then made at Day 3 (Visit 3), Day 6 (Visit 4), and Day 9 (Visit 5) with the potential for 4 additional treatments in Study 2. Subject progress including wound size was then observed on a bi-weekly basis for up to 24 weeks at a total of 12 visits (Weeks 2-24; Visits 6-17).

We retained Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in January 2015 to lead the Company's interactions and correspondence with the FDA for the dermaPACE®, which have already commenced. MCRA has successfully worked with the FDA on numerous Premarket Approvals (PMAs) for various musculoskeletal, restorative and general surgical devices since 2006.

Working with MCRA, we submitted to FDA a *de novo* petition on July 23, 2016. Due to the strong safety profile of our device and the efficacy of the data showing statistical significance for wound closure for dermaPACE® subjects at 20 weeks, we believe that the dermaPACE® device should be considered for classification into Class II as there is no legally marketed predicate device and there is not an existing Class III classification regulation or one or more approved PMAs (which would have required a reclassification under Section 513(e) or (f)(3) of the FD&C Act). On December 28, 2017, the FDA determined that the criteria at section 513(a)(1)(A) of (B) of the FD&C Act were met and granted the *de novo* clearance classifying dermaPACE® as Class II and available to be marketed immediately.

Finally, our dermaPACE® device 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.

We are actively marketing the dermaPACE® to the European Community, Canada, Brazil, Mexico, and Asia/Pacific, utilizing distributors in select countries.

Clinical Studies

A post-market pilot study to evaluate the effects of high energy focused, acoustic shock wave therapy on local skin perfusion and healing of diabetic foot ulcers was changed to a 15-patient case study with the same primary objective of determining the effects of high-energy focused, acoustic shock wave therapy on oxygen saturation levels was completed. A near-infrared spectroscopy device was used to measure the oxygen saturation levels prior to treatment and after the full treatment regimen. Treatment with the dermaPACE® System resulted in all patients demonstrating a statistically significant increase in tissue oxygen saturation within the wound bed, a key component of wound healing. Additionally, the results showed all 15 wounds demonstrated a decrease in wound area and seven of the wounds healed. The results of this case study are another indication that treatment of Diabetic Foot Ulcers with the dermaPACE® System prepares the wound bed via oxygenation and neo-vascularization, facilitating accelerated wound resolution via the body's natural healing process or preparing the wound to more readily respond to other advanced healing modalities.

UltraMIST® - Ultra sound healing Therapy

UltraMIST® is an FDA approved powerful, non-contact and non-thermal ultrasound therapy device used to promote wound healing. UltraMIST® is FDA approved to treat malaises such as diabetic foot ulcers, pressure ulcers, venous leg ulcers, deep tissue pressure injuries, and surgical wounds. Currently, the Company's dermaPACE® is only approved to treat diabetic foot ulcer.

UltraMIST® currently has over 900 customers in 46 states providing the Company with a robust product offering in the advanced wound care market and an end-to-end advanced wound care product portfolio that addresses the entire care pathway.

Biologic Products

BIOVANCE is a graft skin substitute product that provides a natural foundation for wound healing. The product is an allograft that is prepared from the amnion, the part of the amniotic sac closest to the developing embryo. Key cells and proteins move into the BIOVANCE material so that tissues can regenerate, and wounds can continue to heal. The product is adaptable and flexible, it can conform to irregular surfaces. It is also adaptable in that it can be sutured or glued if determined by the clinician to be a better option. The product also has a 5-year shelf life at room temperature conditions and is available in multiple sizes for application flexibility.

Interfyl is a liquid product that replaces damaged integumental soft tissue and augments / supplements inadequate connective tissues. Interfyl is comprised of allogenic decellularized particulate human placental connective tissue matrix that is placed on a wound. The product repairs small surgical defects resulting from either medical or surgical conditions, including patients with exposed vital structures such as bone, tendon, ligament, or nerves. Interfyl has the ability to fill irregular spaces or soft tissue deficits resulting from trauma or surgery. The filler also allows for cell adherence and growth during tissue repair and affords structural support and elasticity in the tissue. The product is offered in a 1.5mL flowable format in a 3-mL syringe. 50mg and 100mg particulates are in each vial.

Growth Opportunity in Wound Care Treatment

We are focused on the development of products that treat unmet medical needs in large market opportunities. Our FDA approval in the United States for our lead product candidate, dermaPACE®, 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. According to a 2020 report by the Centers for Disease Control and Prevention based on estimated 2018 data, approximately 34.1 million people aged 18 years or older (diagnosed and undiagnosed), roughly 13.0% of the United States population, have diabetes and 1.5 million new cases of diabetes were diagnosed in people aged 18 years or older. In 2016, there were 7.8 million hospital discharges with diabetes as a listed diagnosis. The estimated total direct and indirect costs of diagnosed diabetes in the United States in 2017 was $327 billion. Between 2012 and 2017, medical costs per person associated with diabetes increased from $8,417 to $9,601. Approximately 2 - 7% of diabetics will develop a diabetic foot ulcer each year. Foot ulcers are a significant complication of diabetes mellitus and often precede lower-extremity amputation. The most frequent underlying etiologies are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease. Over 50% of Diabetic foot ulcers will become infected, resulting in high rates of hospitalization, increased morbidity and potential lower extremity amputation and up to 80% of Diabetic foot ulcers that have healed will re-ulcerate within 12 months. According to the International Diabetes Federation 2019 Global Fact Sheet, approximately 463 million people has diabetes and 10% of global health expenditure is spent on diabetes (approximately $760 billion).

A majority of challenging wounds are non-healing chronic wounds and in addition, chronic diabetic foot ulcers and pressure ulcers are often slow-to-heal wounds, which often fail to heal for many months, and sometimes, for several years. These wounds often involve physiologic, complex and multiple complications such as reduced blood supply, compromised lymphatic systems or immune deficiencies that interfere with the body's normal wound healing processes. These wounds often develop due to a patient's impaired vascular and tissue repair capabilities. Wounds that are difficult to treat do not always respond to traditional therapies, which include hydrocolloids, hydrogels and alginates, among other treatments. We believe that physicians and hospitals need a therapy that addresses the special needs of these chronic wounds with high levels of both clinical and cost effectiveness.

We believe we are developing a safe and advanced technology in the wound healing and tissue regeneration market with PACE. dermaPACE® is noninvasive and does not require anesthesia, making it a cost-effective, time-efficient and painless approach to wound care. Physicians and nurses look for therapies that can accelerate the healing process and overcome the obstacles of patients' compromised conditions and prefer therapies that are easy to administer. In addition, since many of these patients are not confined to bed, healthcare providers want therapies that are minimally disruptive to the patient's or the caregiver's daily routines. 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.

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 device features four types of applicators including a unique applicator that is less painful for some indications and may reduce or completely 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

We believe there are significant opportunities in the worldwide orthopedic market, driven by aging baby boomers and their desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to musculoskeletal tissues and/or impair the ability of the body to heal injuries.

We have experience in the sports medicine field (which generally refers to the non-surgical and surgical management of cartilage, ligament and tendon injuries) through our legacy devices, OssaTron and Evotron. 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. Cartilage, ligament and tendons seldom return to a pre-injury state of function. Due to a lack of therapies that can activate healing and regenerate these tissues, many of these injuries will result in a degree of permanent impairment and chronic pain. 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. We plan to submit to U.S. FDA a 510(k) seeking clearance for general indications to address this growing field.

Additionally, we have 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 non-invasive delivery of therapeutic shockwaves for its treatment can help to serve this market.

Non-Medical Uses for Our Shockwave Technology

We believe there are significant license/partnership opportunities for our acoustic pressure shockwave technology in non-medical uses, including in the energy, water, food, and industrial markets.

Due to their powerful pressure gradients and localized cavitational effects, we believe that high-energy, acoustic pressure shockwaves can be used to clean, in an energy efficient manner, contaminated fluids from impurities, bacteria, viruses, and other harmful micro-organisms, which provides opportunities for our technology in cleaning industrial and domestic/municipal waters. Based on the same principles of action of the acoustic pressure shockwaves against bacteria, viruses, and harmful micro-organisms, we believe our technology can be applied for cleaning or sterilization of various foods such as milk, natural juices, and meats.

In the energy sector, we believe that the acoustic pressure shockwaves can be used to improve oil recovery (IOR), as a supplement to or in conjunction with existing fracking technology, which utilizes high pressurized water/gases to crack the rocks that trapped oil in the underground reservoir. Through the use of our high-energy, acoustic pressure shockwaves the efficiency can be improved and at the same time the environmental impact of the fracking process can be reduced. Furthermore, we believe our technology can be used for enhanced oil recovery (EOR) based on the changes in oil flow characteristics resulting from acoustic pressure shockwave stimulation, as a tertiary method of oil recovery from older oil fields.

Additionally, we demonstrated through three studies performed at Montana State University that high-energy, acoustic pressure shockwaves are disrupting biofilms and thus can be used for surface cleaning monuments, ship hulls, and underwater structure cleaning, or to unclog pipes in the energy industry (shore or off-shore installations), food industry, and water management industry, which will reduce or eliminate down times with significant financial benefits for maintenance of existing infrastructure. Also, our technology should have a significant environmental impact by eliminating or reducing the use of harmful chemicals, which are the preferred biofilm cleaning method at this time.

Market Trends

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

According to AdvaMed and Centers for Medicare & Medicaid Services data from 2006 and our internal projections, the United States advanced wound healing market for the dermaPACE® is estimated at $20 billion, which includes diabetic foot ulcers, pressure sores, burns and traumatic wounds, and chronic mixed leg ulcers. We also believe there are significant opportunities in the worldwide orthopedic and spine markets, driven by aging baby boomers and their desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

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, we believe 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. We believe 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 research, development, and 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 end-to-end wound care portfolio of regenerative medicine products and product candidates help restore the body's normal healing processes. SANUWAVE applies and researches its patented energy transfer technologies in wound healing, orthopedic, plastic/cosmetic, and cardiac/endovascular conditions.

Through our August 2020 acquisition of the UltraMIST® System, we now combine two highly complementary and market-cleared energy transfer technologies used in the dermaPACE® and UltraMIST® medical device Systems, which creates a platform of scale in the advanced wound care market.

Our the dermaPACE® device for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. On December 28, 2017, the U.S. FDA granted the Company's request to classify the dermaPACE® System as a Class II device via the *de novo* process. As a result of this decision, the Company was able to immediately market the product for the treatment of diabetic foot ulcers as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions.

Our immediate goal for our regenerative medicine technology involves leveraging the knowledge we gained from our existing human heel and elbow indications to enter the advanced wound care market with innovative treatments.

The key elements of our strategy include the following:

- ***Commercialize and support the domestic distribution of our dermaPACE® device to treat diabetic foot ulcers.***

  We initially focused on obtaining FDA approval in the United States for our lead product candidate, dermaPACE®, for the treatment of diabetic foot ulcers, which we believe represents a large, unmet need.

  On December 28, 2017, the FDA granted the Company's request to classify the dermaPACE® System as a Class II device via the *de novo* process. As a result of this decision, the Company was able to immediately market the product for the treatment of diabetic foot ulcers as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

  We began the commercialization of dermaPACE® in the United States in 2018 through strategic partnership and have continued commercialization in 2019 through placement of devices in doctors' offices, wound care centers and hospitals by our internal sales team. For example, in February 2018, we entered into an agreement with Premier Shockwave Wound Care, Inc. ("PSWC") and Premier Shockwave, Inc. ("PS") for the purchase by PSWC and PS of dermaPACE® Systems and related equipment sold by us and granting PSWC and PS limited but exclusive distribution rights to provide dermaPACE® Systems to certain government healthcare facilities in exchange for the payment of certain royalties to us. PSWC is a related party since it is owned by A. Michael Stolarski, a member of the Company's board of directors and an existing shareholder of the Company.

- ***Develop and commercialize our noninvasive biological response activating devices in the regenerative medicine area for the treatment of skin, musculoskeletal tissue and vascular structures.***

  We intend to use our proprietary technologies and know-how in the use of high-energy, acoustic pressure shock waves to address unmet medical needs in wound care, orthopedic, plastic/cosmetic and cardiac indications, possibly through potential license and/or partnership arrangements.

- ***License and seek partnership opportunities for our non-medical acoustic pressure shock wave technology platform, know-how and extensive patent portfolio.***

  We intend to use our acoustic pressure shock wave technology and know-how for non-medical uses, including energy, food, water cleaning and other industrial markets, through license/partnership opportunities.

- ***Support the global distribution of our products.***

  Our portfolio of products, the dermaPACE® and orthoPACE, are CE Marked and sold through select distributors in certain countries in Europe, Canada, Asia and Asia/Pacific. Our revenues will continue from sales of the devices and related applicators in these markets. We intend to continue to add additional distribution partners in the Americas, Middle East, Africa, Europe and Asia/Pacific.

Scientific Advisors

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

We pay 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

Following FDA approval in December 2017, we sought a development and/or commercialization partnership, or to commercialize the product ourselves domestically, including the commercialization of the assets obtained in the Asset Purchase Agreement with our internal sales force. Outside the United States, we retain distributors to represent our products in selective international markets. These distributors have been selected based on their existing business relationships and the ability of their sales force and distribution capabilities to effectively penetrate the market with our PACE product line. We rely on these distributors to manage physical distribution, customer service and billing services for our international customers.

For a period of approximately three months following the August 6, 2020 Asset Purchase Agreement, we utilized the seller to fulfill certain customer orders and to collect related accounts receivable payments from customer orders that originated from the acquired business after August 6, 2020. For the year ended December 31, 2020, orders fulfilled by the seller comprised approximately 41% of the Company's 2020 full year revenues. As of December 31, 2020, accounts receivable balances that originated from these seller-fulfilled orders constituted approximately 46% of accounts receivable balances, all of which were either reserved as of December 31, 2020 or subsequently collected during 2021. For the year ended December 31, 2021, orders fulfilled by the seller comprised approximately 16% of the accounts receivable balances, and one other vendor comprised approximately 24% of the accounts receivable balances.

Manufacturing

We have developed a network of suppliers, manufacturers and contract service providers to provide sufficient quantities of our products.

We are 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 (EN ISO 13485) and applicable industry and regulatory standards. We produce the applicators and applicator kits for our products. In addition, we program and load software for both the generator boxes and applicators and perform the final product testing and certifications internally.

Our facility in Suwanee, Georgia consists of 10,177 square feet and provides office, research and development, quality control, production and warehouse space. It is a FDA registered facility and is ISO 13485:2016 and Medical Device Single Audit Program ("MDSAP") certified (for meeting the requirements for a comprehensive management system for the design and manufacture of medical devices).

We are 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 (EN ISO 13485) and applicable industry and regulatory standards. In addition, we perform the final product testing for generators and treatment wands internally. Please see further information regarding a dispute with this supplier in Note 25, Subsequent Events.

We are 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 (EN ISO 13485) and applicable industry and regulatory standards. We produce 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 ISO 13485:2016.

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. We seek 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

We consider the protection afforded by patents important to our business. We intend to seek and maintain patent protection in the United States and select foreign countries, where deemed appropriate for products that we develop. 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 we do not avoid infringement of the intellectual property rights of others, we 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.

We derive our patent rights, including as to both issued patents and "patent pending" applications, from three sources: (1) assignee of patent rights in technology we developed; (2) assignee of patent rights purchased from HealthTronics, Inc. ("HealthTronics"); and (3) as licensee of certain patent rights assigned to HealthTronics. In August 2005, we purchased a significant number of patents and patent applications from HealthTronics, to whom we granted back perpetual and royalty-free field-of-use license rights in the purchased patent portfolio primarily for urological uses. We believe 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 we have patented. However, we do not hold patent rights that cover all of our products, product components, or methods that utilize our products. We also have 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.

On the shockwave technology, we are the assignee of thirty-four (34) issued United States patents and forty-seven (47) issued foreign patents that are not expired, which on average have remaining useful lives of ten years with the longest useful life extending to 2039. On the ultrasound technology, we are the assignee of seventeen (17) issued United States patents and twenty-three (23) issued foreign patents that are not expired, which on average have remaining useful life extending to 2028. Our current issued United States and foreign patents include patent claims directed to particular electrode configurations for shockwave devices, piezoelectric fiber shockwave devices, chemical components for shockwave generation, reflector geometries for focused shockwaves, general medical systems general construction, non-contact and low-frequency ultrasound device construction, disposable applicator for ultrasound devices, ultrasonic catheter for drug delivery, ultrasonic method for wound treatment, combination of ultrasound and laser in wound care, and software architecture for licensing processes. Our United States patents also include patent claims directed to methods and devices such as our products for using acoustic pressure shockwaves or non-contact and low frequency ultrasound to treat ischemic conditions, spinal cord scar tissue and spinal injuries, bone fractures and osteoporosis, blood sterilization, stem cell stimulation, tissue cleaning, and within particular treatment parameters using personalized medical treatments for diabetic foot ulcers or pressure sores or venous ulcers or arterial ulcers or acute skin conditions. Also, we have a significant number of US and international patents related to the extracorporeal or intracorporeal use of shockwaves or pressure waves for cardiovascular field (plaque removal, elimination of occlusions, treatment of heart tissue ischemia, to name a few). While such patented method and device claims may provide patent protection against certain indirect infringing promotion and sales activities of competing manufacturers and distributors, certain medical methods performed by medical practitioners or related health care entities or methods executed by industrial operators may be subject to exemption from potential infringement claims under 35 U.S.C. § 287(c) and, therefore, may limit enforcement of claims of our medical and non-medical method patents as compared to device construction patents.

We also currently maintain for shockwave technology twelve (12) United States patent applications and nineteen (19) foreign patent applications. Our patent-pending rights include inventions directed to certain shockwave devices and systems, ancillary products, and components for acoustic pressure shockwave treatment devices, and various methods of using acoustic pressure shockwaves in both medical and non-medical applications. The medical patent-pending methods include, for example, using acoustic pressure shockwaves to treat soft tissue disorders, bones, joints, wounds, skin, blood vessels, lymphatic disorders, cardiac tissue, fat and cellulite, lung tissue, or to facilitate vaccination, or to disinfect reusable devices as ventilators and endoscopes, and for the use of shockwaves in combination with other energy medical technologies. In the non-medical field, the use of acoustic pressure shockwaves for blood and fluids sterilization, to facilitate oil extraction and processing, to destroy different pathogens from installation and different devices, to process fluids, meat and dairy products, to achieve desalination and decontamination of radio-active waters, and to clean transport pipes.
For the ultrasound technology, we currently maintain two (2) United States patent applications and eight (8) foreign patent applications. Our patent-pending rights include inventions directed to non-contact and low-frequency ultrasound systems and methods for delivering cellular and biological materials to tissues and new designs used to deliver ultrasonic therapies to wound care.
All our United States and foreign pending applications either have yet to be examined or require response to an examiner's office action rejections and, therefore, remain subject to further prosecution, the possibility of further rejections and appeals, and/or the possibility we may elect to abandon prosecution, without assurance that a patent may issue from any pending application.

Under our license to HealthTronics, we reserve exclusive rights in our purchased portfolio as to orthopedic, tendonopathy, skin wounds, cardiac, dental, neural medical conditions and to all conditions in animals (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 (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. Refer to section "Contractual Obligations" for information on the default of our loan with HealthTronics.

Pursuant to mutual amendment and other assignment-back rights under the patent license agreement with HealthTronics, we are also a licensee of certain patents and patent applications that have been assigned to HealthTronics. We 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.

As part of the sale of the veterinary business in June 2009, we have also granted certain exclusive and non-exclusive patent license rights to Pulse Veterinary Technologies, LLC for most of our medical patent portfolio issued before 2009 to utilize acoustic pressure shockwave technologies in the field of non-human mammals.

Given our international patent portfolio, there are growing risks of challenges to our existing and future patent rights. Such challenges may result in invalidation or modification of some or all of our patent rights in a particular patent territory and reduce our competitive advantage with respect to third party products and services. Such challenges may also require the expenditure of significant financial and managerial resources.

If we become 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, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we 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, we believe that our product brand names are an important factor in establishing and maintaining brand recognition.

We have 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, now SANUWAVE is the owner of the Celleration® (United States, Australia, Europe Community, and Japan), Proven Healing® (Madrid Protocol, European Community, and United Kingdom), MIST Ultrasound Healing Therapy & Design® (United States), MIST® (United States), MIST Therapy® (United States), and MIST & Design® (United States) registered trademarks.

We also maintain trademark registrations for: OssaTron® (United States), OSWT® (Switzerland) Evotron® (United States, Germany and Switzerland), Evotrode® (United States, Germany and Switzerland), Orthotripsy® (United States). We 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.

Potential Intellectual Property Issues

Although we believe that the patents and patent applications, including those that we license, provide a competitive advantage, the patent positions of biotechnology and medical device companies are highly complex and uncertain. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Our success will depend in part on us not infringing on patents issued to others, including our competitors and potential competitors, as well as our ability to enforce our patent rights. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products and product candidates, or to obtain and use information that we regard as proprietary. In enforcement proceedings in Switzerland, we assisted HealthTronics as an informer of misappropriation by a Swiss company called SwiTech and related third parties of intellectual property rights in legacy proprietary software and devices relating to assets we purchased from HealthTronics in August 2005. As a result of this action, SwiTech was forced into bankruptcy. We also pursued the alleged misappropriation by another Swiss company called SwiTalis and related third parties of intellectual property rights in legacy proprietary software and devices relating to assets we purchased from HealthTronics in August 2005. In 2016, SwiTalis claimed copyright rights on the High Voltage Modules that were used in our devices and the old line of Pulse Vet devices during the manufacturing process at Swisstronics in Switzerland. At this time, however, no such court action against Swisstronics is pending in Switzerland and we believe that it is unlikely that SwiTalis will pursue their earlier allegations against Swisstronics and, indirectly, us. In 2017, we abandoned our action against SwiTalis. There can be no assurance, however, that future claims or lawsuits against us may not be brought, and such present or future actions against violations of our intellectual property rights may result in us incurring material expense and divert the attention of management.

Third parties that license our proprietary rights, such as trademarks, patented technology or copyrighted material, may also take actions that diminish the value of our proprietary rights or reputation. In addition, the steps we take to protect our proprietary rights may not be adequate and third parties may infringe or misappropriate our copyrights, trademarks, trade dress, patents, and similar proprietary rights.

We collaborate with other persons and entities on research, development, and commercialization activities and expect to do so in the future. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, researchers, licensors, licensees and consultants. In addition, other parties may circumvent any proprietary protection that we do have. As a result, we may not be able to maintain our proprietary position.

Competition

We believe 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 (formerly Kinetic Concepts, Inc.), 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) 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., and CellSonic Medical which could ultimately pursue the wound care market. Nevertheless, we believe that the dermaPACE® System has 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.

Developing and commercializing new products is highly competitive. The market is characterized by extensive research and clinical efforts and rapid technological change. We face intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major pharmaceutical companies. We 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. In order 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 we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products, and we 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 also 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, we 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, we 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.

In the past, the 510(k) pathway for product marketing required only the proof of significant equivalence in technology for a given indication with a previously cleared device. Currently, there has been a trend of the FDA requiring additional clinical work to prove efficacy in addition to technological equivalence. Thus, no matter which regulatory pathway we may take in the future towards marketing products in the United States, we will be required to provide clinical proof of device effectiveness.

Within the past few years, the FDA has released guidelines for the FDA's reviewers to use during a product's submission review process. This guidance provides the FDA reviewers with a uniform method of evaluating the benefits verses the risks of a device when used for a proposed specific indication. Such a benefit/risk evaluation is very useful when applied to a novel device or to a novel indication and provides the FDA with a consistent tool to document their decision process. While intended as a guide for internal FDA use, the public availability of this guidance allows medical device manufacturers to use the review matrix to develop sound scientific and clinical backup to support proposed clinical claims and to help guide the FDA, through the decision process, to look at the relevant data. We intend to use this benefit/risk tool in our FDA submissions.

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. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances where the FDA has not. If the FDA finds the information satisfactory, it will approve the PMA. 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.

During the review of either a PMA application or 510(k) submission, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. We cannot be sure that our product candidates will be approved or cleared in a timely fashion or at all. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

Obtaining medical device clearance, approval, or licensing in the United States or abroad can be an expensive process. The fees for submitting an original PMA to the FDA for consideration of device approval are substantial. Fees for supplement PMA's are less costly but still can be substantial. International fee structures vary from minimal to substantial, depending on the country. In addition, we are 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, we are 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, we may not qualify for the Small Business Manufacturer reduced fee amounts and will be required to pay full fee amounts.

Clinical Trials of Medical Devices

One or more clinical trials are almost always required to support a PMA application and more recently are becoming necessary to support a 510(k) submission. Clinical studies of unapproved or un-cleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board (IRB) has approved the study.

During the study, the sponsor must comply with the FDA's IDE requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. We, the FDA, or the IRB at each institution at which a clinical trial is being conducted, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

However, the COVID-19 pandemic has impacted our ability to enroll and treat patients in clinical trials and to monitor data at our clinical trial sites.

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 (QSR), 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 also follow-on, confirmatory studies.

We continue 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 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 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 we can use it. We 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.

The primary regulatory environment in Europe is the European Union, which consists of 27 member states encompassing most of the major countries in Europe. In the European Union, the European Medicines Agency (EMA) and the European Union Commission have determined that dermaPACE®, orthoPACE, OssaTron and Evotron will be regulated as medical device products. These devices have been determined to be Class IIb devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area.

The primary regulatory body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have an ISO 13485 certification, as well as meet additional requirements of Canadian laws. We currently maintain this certification. We maintain a device license for dermaPACE® with Health Canada for the indication of "devices for application of shock waves (pulsed acoustic waves) on acute and chronic defects of the skin and subcutaneous soft tissue".

The primary regulatory bodies and paths in Asia and Australia are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485.

The primary regulatory body in Brazil is ANVISA, all medical devices imported into or distributed within Brazil must first undergo registration with ANVISA. Once ANVISA makes its final decision on registration applications, the result is published in Brazil's Official Diary, in addition to ANVISA, our products require additional certification via INMETRO. We currently hold a Class II device licenses in BRAZIL for dermaPACE® and is in the process of registering our UltraMIST® product line

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to current good manufacturing practice (cGMP), as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with cGMP is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a Notified Body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The Competent Authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the Notified Body. Further inspections may occur over the life of the product.

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. These third-party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third-party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third-party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the products or therapies. 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 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.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use products, including ours.

One of the components in the reimbursement decision by most private insurers and governmental payers, including the Centers for Medicare & Medicaid Services, which administers Medicare, is the assignment of a billing code. Billing codes are used to identify the procedures performed when providers submit claims to third party payers for reimbursement for medical services. They also generally form the basis for payment amounts. We will seek new billing codes for the wound care indications of our products as part of our efforts to commercialize such products.

The initial phase of establishing a professional billing code for a medical service typically includes applying for a CPT Category III code for both hospital and in-office procedures. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as American Medical Association (AMA) CPT Editorial Panel review. A new CPT Category III code will be assigned if the AMA CPT Editorial Panel committee deems it meets the applicable criteria and is appropriate. In 2017, we applied for two, new CPT Category III codes for extracorporeal shock wave therapy (ESWT) in wound healing. These codes were published by AMA/CPT for use beginning January 1, 2019.

The secondary phase in the CPT billing code process includes the establishment of a permanent CPT Category I code in which relative value is analyzed and established by the AMA. The approval of this code is based on, among other criteria, widespread usage and established clinical efficacy of the medical service.

There are also billing codes that facilities, rather than health care professionals, utilize for the reimbursement of operating costs for a particular medical service. For the hospital outpatient setting, the Centers for Medicare & Medicaid Services automatically classified the new ESWT wound healing CPT Category III codes into interim APC groups. The APC groups are services grouped together based on clinical characteristics and similar costs. An APC classification does not guarantee payment.

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 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 ("ARRA") 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. Rules implementing various aspects of HIPAA are continuing to be promulgated.

We anticipate that, as we expand our dermaPACE® business, we will in the future be a covered entity under HIPAA. We intend to adopt policies and procedures 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.

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, 2021, we had a total of 40 full time employees in the United States. Of these, eight 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 is 3360 Martin Farm Road, Suite 100 Suwanee, Georgia 30024, and our main telephone number is (770) 419-7525.

Available Information

We make available free of charge through our website - www.sanuwave.com - our periodic reports and registration statements filed with the United States Securities and Exchange Commission (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 Form 10-K. The SEC also maintains a website at www.sec.gov that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC.

Item 1A. RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this 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.

Below is a summary of the Risk Factors that are reported in this 10-K for reference. The full report of Risk Factors follows the summary.

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.
- We have a history of losses, and we may continue to incur losses and may not achieve or maintain profitability.
- 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.
- The coronavirus, or COVID-19, pandemic has materially and adversely affected our clinical trial operations and may materially and adversely affect our financial results.
- Our product candidates may not be developed or commercialized successfully.
- 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.
- If our products and product candidates do not gain market acceptance among physicians, patients and the medical community, we may be unable to generate significant revenues, if any.
- 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.
- 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 currently sell our products through distributors and partners. Our business and results of operations could be adversely affected by any business disruptions or credit or other financial difficulties experienced by such distributors or partners.
- 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.
- The loss of our key management would likely hinder our ability to execute our business plan.
- We face an inherent risk of liability in the event that the use or misuse of our product candidates results in personal injury or death.
- We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.
- 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.
- Provisions in our Articles of Incorporation, Bylaws and Nevada law might decrease the chances of an acquisition.

Regulatory Risks

- The results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates.
- We are subject to extensive governmental regulation, including the requirement of FDA approval or clearance, before our product candidates may be marketed.
- Patients may discontinue their participation in our clinical studies, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.
- We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.
- We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.
- Regulatory approval of our product candidates may be withdrawn at any time.
- Federal regulatory reforms may adversely affect our ability to sell our products profitably.
- Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.
- 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.
- Uncertainty surrounding and future changes to healthcare law in the United States may have a material adverse effect on us.
- 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.
- 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.
- 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.
- 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 use of hazardous materials in our operations may subject us to environmental claims or liability.

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.
- 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.
- Our patents may not be valid or enforceable and may be challenged by third parties.
- Issued patents and patent licenses may not provide us with any competitive advantage or provide meaningful protection against competitors.
- The ability to market the products we develop is subject to the intellectual property rights of third parties.

Risks Related to our Common Stock

- Our stock price is volatile.
- There is currently a limited trading market for our common stock and we cannot predict how liquid the market might become.
- 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.
- As an issuer of "penny stock", the protection provided by the federal securities laws relating to forward looking statements does not apply to us.
- 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.
- The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

- We have not sought an advisory stockholder vote to approve the compensation of our named executive officers.
- Because we did not comply with our SEC filing obligations, our stock may become subject to limitations or reduction in stock price, liquidity, or volume.
- We will need to improve our internal controls and procedures in order to remain current with our securities-related requirements.

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 dermaPACE® 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 $27.3 million and $30.9 million for the years ended December 31, 2021 and 2020, 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 Form 10-K.

As of December 31, 2021, we had an accumulated deficit of $183.9 million and cash and cash equivalents of $619 thousand. For the years ended December 31, 2021 and 2020, the net cash used by operating activities was $6.7 million and $12.7 million, respectively. Cash used in operations averaged $1.1 million per month in the first quarter of 2021, approximately $700 thousand for the second quarter, approximately $400 thousand for the third quarter and approximately $50 thousand for the fourth quarter.

The continuation of our business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2022 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or 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 shareholders. 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. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions 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 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 have a history of losses, and we may continue to incur losses and may not achieve or maintain profitability.

For the year ended December 31, 2020, we had a net loss of $27.3 million and used $6.7 million of cash in operations. As of December 31, 2021, we had an accumulated deficit of $183.9 million and a total stockholders' deficit of $39.0 million. For the year ended December 31, 2020, we had an accumulated deficit of $156.7 million and a total stockholders' deficit of $13.7 million. As a result of our significant research, clinical development, regulatory compliance and general and administrative expenses, we expect to incur losses as we continue to incur expenses related to commercialization of the dermaPACE® System and research and development of the non-medical uses of the PACE technology. Even if we succeed in developing and commercializing the dermaPACE® System or any other product candidates, we may not be able to generate sufficient revenues and we may never achieve or be able to maintain profitability.

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 convertible promissory notes, the issuance of notes payable to related parties, the issuance of promissory notes, the sale of our veterinary division in June 2009 and product sales. We will seek to obtain additional funds in the future through equity or debt financings, or 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 alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant 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;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using any of our approved products;
- inability to train a sufficient number of physicians to create a demand for any of our approved products;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- unforeseen problems with our third-party manufacturers, service providers or specialty suppliers of certain raw materials;
- unanticipated difficulties in operating in international markets;
- unanticipated financial resources needed to respond to technological changes and increased competition;
- unforeseen problems in attracting and retaining qualified personnel;
- the impact of 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.

The coronavirus, or COVID-19, pandemic has materially and adversely affected our clinical trial operations and may materially and adversely affect our financial results.

The COVID-19 pandemic has affected many countries, including the United States and several European countries, where we are currently conducting clinical trials. In response to the pandemic, hospitals participating in the trials in affected countries have taken a number of actions, including restricting elective and other procedures that are not deemed to be life-threatening, suspending clinical trial activities and limiting access to data monitoring. As a result, patients enrolled in our clinical trials have had the start of their treatments postponed and ongoing treatment regimens may be delayed. In addition, we do not have sufficient access to monitor trial data on a timely basis. These restrictions have had a materially adverse impact on our clinical operations. The extent to which the COVID-19 pandemic may impact our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the spread and severity of COVID-19, and the effectiveness of governmental actions in response to the pandemic. Furthermore, the spread of COVID-19 may materially impact our ability to recruit and retain patients.

These consequences of the COVID-19 pandemic will delay and could adversely affect our ability to obtain regulatory approval for and to commercialize our products, increase our operating expenses, and could have a material adverse effect on our financial results.

Our product candidates may not be developed or commercialized successfully.

Our product candidates are based on a technology that has not been used previously in the manner we propose and must compete with more established treatments currently accepted as the standards of care. 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 FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- 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.

In addition, our product development program may be curtailed, redirected, eliminated or delayed at any time for many reasons, including:

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;
- the inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our trials; and
- regulatory delays or other regulatory actions.

We cannot predict whether we will successfully develop and 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.

In 2019, Tissue Regeneration Technologies, LLC obtained clearance from the FDA for treatment of diabetic foot ulcers using non-focused shockwaves, as a 510(k) submission based on our dermaPACE® System *de novo* clearance. We take issue with the FDA's decision regarding substantial equivalence of the unfocused shockwave technology with the focused shockwave technology that we are marketing. The so-called unfocused shockwaves, which in reality are pressure waves and not shockwaves, produce much lower energy compared to focused shockwaves, which makes the two technologies non-equivalent in energy output in the treatment zone.

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 also compete with our competitors in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to our programs or advantageous to our business.

If our products and product candidates do not gain market acceptance among physicians, patients and the medical community, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates, they may not gain market acceptance among physicians, healthcare payers, patients and the medical community. Market acceptance will depend on our ability to demonstrate the benefits of our approved products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness. In addition, we believe market acceptance depends on the effectiveness of our marketing strategy, the pricing of our approved products and the reimbursement policies of government and third-party payers. Physicians may not utilize our approved products for a variety of reasons and patients may determine for any reason that our product is not useful to them. If any of our approved products fail to achieve market acceptance, our ability to generate revenues will be limited.

In addition, a significant health epidemic could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect the market for our products, which could have a material adverse effect on our business, operating results and financial condition.

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, including possibly the design and manufacture of product materials, potentially 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 effect by supply chain problems resulting from the pandemic. Due to these disruptions, we have experienced a few small backorder situations on our UltraMIST® applicators. 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, then 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 currently sell our products through distributors and partners. Our business and results of operations could be adversely affected by any business disruptions or credit or other financial difficulties experienced by such distributors or partners.

For a period of approximately three months following the August 6, 2020 Asset Purchase Agreement, we utilized the seller to fulfill certain customer orders and to collect related accounts receivable payments from customer orders that originated from the acquired business after August 6, 2020. For the year ended December 31, 2020, orders fulfilled by the seller comprised approximately 49% of the Company's 2020 full year revenues. As of December 31, 2020, accounts receivable balances that originated from these seller-fulfilled orders constituted approximately 46% of accounts receivable balances, all of which were either reserved as of December 31, 2020 or subsequently collected during 2021. For the year ended December 31, 2021, orders fulfilled by the seller comprised approximately 16% of the accounts receivable balances, and one other vendor comprised approximately 24% of the accounts receivable balances.

To the extent that our distributors or partners experience any business disruptions or credit or other financial difficulties, our revenues and the collectability of our accounts receivable could be negatively impacted. If we are unable to establish, on a timely basis, relationships with new distributors or partners, our business and results of operations could be negatively impacted.

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, the Company 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. Michael Stolarski, 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 us, 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 stockholder in the event that 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 50 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 in the event that the use or misuse of our product candidates results in personal injury or death.

The use of our product candidates in clinical trials and the sale of any approved 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, which 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 product for which we obtain approval 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 a number of difficulties and risks, including:

- 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;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- 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.

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 and Bylaws that implement these are:

- stockholders may not vote by written consent;
- advance notice of business to be brought is required for a meeting of the Company's 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

The results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate is safe and effective in advanced clinical trials involving large numbers of patients, we will be unable to submit the necessary application to receive regulatory approval to commercialize the product candidate. We face risks that:

- the product candidate may not prove to be safe or effective;
- the product candidate's benefits may not outweigh its risks;
- the results from advanced clinical trials may not confirm the positive results from pre-clinical studies and early clinical trials;
- the FDA or comparable foreign regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than us; and
- the FDA or other regulatory agencies may require additional or expanded trials and data.

We are subject to extensive governmental regulation, including the requirement of FDA approval or clearance, before our product candidates may be marketed.

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected. The FDA has determined that our technology and product candidates constitute "medical devices" and are thus subject to review by the Center for Devices and Radiological Health. However, we 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 applicable governmental review requirements could vary in some respects and be more lengthy and costly.
Both before and after approval or clearance of our product candidates, 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;
- delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval and clearance requirements, numerous other regulatory requirements apply, both before and after approval or clearance, 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.

Patients may discontinue their participation in our clinical studies, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Clinical trials for our product candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged to be related to our product candidates under evaluation. If a large number of patients in a study discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of the product candidate.

In addition, the time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the following:

- the size of the patient population;
- the nature of the clinical protocol requirements;
- the availability of other treatments or marketed therapies (whether approved or experimental);
- our ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient eligibility criteria for the study.

We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our device.

We engage a clinical research organization (CRO) and other third-party vendors to assist in the conduct of our clinical trials. There are numerous sources that are capable of providing these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials, the commercial prospects for the product could be harmed and our ability to generate product revenues would be delayed or prevented. Any failure of the CRO and other third-party vendors to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services they provide for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our product and obtain regulatory approval. Problems with the timeliness or quality of the work of the CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our clinical trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for several reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

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.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

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 and marketing of a medical device. 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. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes on us, if any, may be.

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.

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 product and product candidates, 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 or product candidates 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.

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 as a result of regulatory reform. In March 2010, the former U.S. President signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the PPACA), which substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the biotechnology and medical device industries. The PPACA, as amended, includes, among other things, the following measures:

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biological products that are demonstrated to be biosimilar or interchangeable with a licensed biological product.

However, some of the provisions of the PPACA have yet to be fully implemented and certain provisions have been subject to judicial, Presidential and Congressional challenges. In addition, the U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In the coming years, there may continue to be additional proposals relating to the reform of the United States healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations and financial condition.

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in the United States and other markets. We could experience an adverse impact on our operating results due to increased pricing pressure these markets. Governments, hospitals and other third-party payors 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 similar to 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.

All of 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 are in compliance 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 dermaPACE® business, we will in the future be a covered entity under HIPAA. We intend to adopt policies and procedures 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 privacy regulations establish a uniform federal standard but do not supersede state laws that may be more stringent. Therefore, as we expand our dermaPACE® business, we may also be required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. The federal privacy regulations restrict the ability to use or disclose certain individually identifiable patient health information, without patient authorization, for purposes other than payment, treatment or health care operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy 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 and state 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 product candidates 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 product candidates; 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 product candidates, 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 product candidates. 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 of our rights 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.

In particular, we cannot assure you that:

- we or the owners or other inventors of the patents that we own or that have been licensed to us, or that may be issued or licensed to us in the future, were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our patent applications will result in issued patents;
- the patents and patent applications that we own or that have been licensed to us, or that may be issued or licensed to us in the future, will provide a basis for commercially viable products or will provide us with any competitive advantages, or will not be challenged by third parties;
- the patents and patent applications that have been licensed to us are valid and enforceable;
- we will develop additional proprietary technologies that are patentable;
- we will be successful in enforcing the patents that we own or license and any patents that may be issued or licensed to us in the future against third parties;
- the patents of third parties will not have an adverse effect on our ability to do business; or
- our trade secrets and proprietary rights will remain confidential.

Accordingly, we may fail to secure meaningful patent protection relating to any of our existing or future product candidates 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 product candidates in countries where we do not have adequate patent protection. Failure to obtain adequate patent protection for our product candidates, 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 product candidates, negatively impact the prices we can charge for our product candidates, 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 in the future. 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 a number of our target markets. The failure to obtain adequate patent protection for our 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 a large number of 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 of 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 are able to 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 as a result 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, 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 the timing of on-going clinical trial enrollment, the results of our clinical trials and regulatory approvals for our product candidates or failure to obtain such regulatory approvals;
- 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 particular 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 September 28, 2021, our common stock was quoted on the OTC Pink Sheets, which is an inter-dealer market that provides significantly less liquidity than the New York Stock Exchange or the Nasdaq Stock Market. The Company was again listed on the OTC Pink Sheet after the filing our Form 10-Q for the quarter ended September 30, 2021. The quotation of our common stock on the OTC Pink Sheets 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.

On January 31, 2020, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series C Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 90 shares of our preferred stock as Series C Convertible Preferred Stock. Although we have no other shares of preferred stock currently outstanding and no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

On January 12, 2016, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series B Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 293 shares of our preferred stock as Series B Convertible Preferred 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.

Because we did not 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 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. The company upon filling the Form 10-Q for the quarter ended September 30, 2021 was allowed to return to the OTC Pink Sheets. With trading on the Pink Sheets 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.

Additionally, as a result of our failure to comply with the SEC filing obligations, as noted above, our stock was delisted from the OTC Pink Market to the OTC Expert Market. The OTC Expert Market is an even more limited market where the stocks are more volatile and poses a greater risk to investors. Since our stock is downgraded, it may be designated with a "stop sign" indicating that current public information about our company is not available due to "delinquent SEC reporting."

We will need to improve our internal controls and procedures in order to remain current with our securities-related requirements.

We are submitting this Annual Report 10-K for the year ended December 31, 2021 after the required SEC filing deadlineAs a result, our failure to maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our stock.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We have an operations, production and research and development office in a leased facility in Suwanee, Georgia, consisting of 10,177 square feet of space under a lease which expired on December 31, 2021, and is now being utilized on a month-by-month basis. Under the terms of the lease, we paid monthly rent of $14,651, subject to a 3% adjustment on an annual basis.

We have another operations and research and development office in 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 of $6,388, subject to a 2.45% adjustment on an annual basis.

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 5. 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 OTC Expert Market 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, 2021, there were 481,619,621 shares of Common Stock outstanding and approximately 198 holders of record of the Company's common stock.

Dividends

The Company has never declared or paid any cash dividends on its common stock. The Company intends to retain future earnings, if any, to finance the expansion of its business. As a result, the Company does not anticipate paying any cash dividends in the foreseeable future.

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 (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	-	$ 0.00	-
Equity compensation plans not approved by security holders	31,409,385	$ 0.28	3,240,615
Total	31,409,385	$ 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 particular 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 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.

HealthTronics

Please see Item 7, "Management Discussion and Analysis-Liquidity and Capital Resources-Convertible Notes Payable" for discussion of the transactions with HealthTronics, including the issuance of a convertible note and other various securities of the Company.

Leviston

Please see Item 7, "Management Discussion and Analysis-Liquidity and Capital Resources-Convertible Notes Payable" for discussion of the transactions with Leviston, including the issuance of a convertible note and other various securities of the Company.

Item 6. [Reserved]

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding our business development plans, clinical trials, regulatory reviews, timing, strategies, expectations, anticipated expenses levels, projected profits, business prospects and positioning with respect to market, demographic and pricing trends, business outlook, technology spending and various other matters (including contingent liabilities and obligations and changes in accounting policies, standards and interpretations) and express our current intentions, beliefs, expectations, strategies or predictions. These forward-looking statements are based on a number of assumptions and currently available information and are subject to a number of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections titled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" and elsewhere in this Annual Report on Form 10-K. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K.

Overview

We are a shock wave technology company using a patented system of noninvasive, high-energy, acoustic shock waves for regenerative medicine and other applications. Our initial focus is regenerative medicine utilizing noninvasive, acoustic shock waves to produce a biological response resulting in the body healing itself through the repair and regeneration of tissue, musculoskeletal, and vascular structures.

Our lead regenerative product in the United States is the dermaPACE® device, used for treating diabetic foot ulcers, which was subject to two double-blinded, randomized Phase III clinical studies. On December 28, 2017, the FDA granted the Company's request to classify the dermaPACE® System as a Class II device via the *de novo* process. As a result of this decision, the Company was able to immediately market the product for the treatment of diabetic foot ulcers as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

On August 6, 2020, we entered into an asset purchase agreement (the "Asset Purchase Agreement" or "Acquisition") with Celularity Inc. ("Celularity") pursuant to which we acquired Celularity's UltraMIST® assets ("UltraMIST®" or the "Assets"). The UltraMIST® System provides through a fluid mist a 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 U.S. Food and Drug Administration (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.

In connection with the Asset Purchase Agreement, on August 6, 2020, we entered into a license and marketing agreement with Celularity pursuant to which Celularity granted to the Company a license to the Celularity wound care biologic products, Biovance® and Interfyl® (the "License Agreement"). The License Agreement provides the Company with an exclusive license to use, market, distribute and sell Biovance® in the "Field" and "Territory" (each as defined in the License Agreement), and a non-exclusive license to use, market, distribute and sell Interfyl® in the Field in the Territory. The License Agreement has an initial five-year term, after which it automatically renews for additional one-year periods, unless either party gives written notice at least 180 days prior to the expiration of the current term. In May 2021, the Company received notification that it is not in compliance with the Biovance portion of the License Agreement with Celularity.

Our portfolio of healthcare products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. We intend to apply our Pulsed Acoustic Cellular Expression (PACE®) technology in wound healing, orthopedic, plastic/cosmetic and cardiac conditions. The Company is marketing its dermaPACE® System for treatment usage in the United States and will continue to generate revenue from sales of the European Conformity Marking (CE Mark) devices and accessories in Europe, Canada, Asia, and Asia/Pacific. The Company generates revenue streams from product sales, licensing transactions, dermaPACE® treatments and other activities, and with its recent acquisition of the UltraMIST® assets, SANUWAVE now combines two highly complementary and market-cleared energy transfer technologies used in the dermaPACE® and UltraMIST® Systems and two human tissue biologic products (Biovance® and Interfyl®), which creates a platform of scale with an end-to-end product offering in the advanced wound care market.

Our lead product candidate for the global wound care market, dermaPACE®, has received FDA clearance for commercial use to treat diabetic foot ulcers in the United States and the CE Mark allowing for commercial use on acute and chronic defects of the skin and subcutaneous soft tissue. We believe we have demonstrated that our patented technology is safe and effective in stimulating healing in chronic conditions of the foot and the elbow through our United States FDA Class III Premarket Approvals ("PMAs") approved OssaTron® device, and in the stimulation of bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of our OssaTron, Evotron®, and orthoPACE® devices in Europe and Asia.

We are focused on developing our Pulsed Acoustic Cellular Expression (PACE) technology to activate healing in:

- 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, 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
- cardiac applications for removing plaque due to atherosclerosis improving heart muscle 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, for sterilizing food liquids and finally for maintenance of industrial installations by disrupting biofilms formation. Our business approach will be through licensing and/or partnership opportunities.

The worldwide spread of the COVID-19 virus is expected to result in a global slowdown of economic activity which is likely to decrease demand for a broad variety of products, including from our customers. We have experienced a disruption of our supply channels which will continue for an unknown period of time until the global supply chain can return to the pre- disease status. Also, the pandemic may cause 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 and we expect that they will continue to have a negative impact on our sales and our results of operations, the size and duration of which we are currently unable to predict.

Clinical Trials and Marketing

The FDA granted approval of our Investigational Device Exemption (IDE) to conduct two double-blinded, randomized clinical trials utilizing our lead device product for the global wound care market, the dermaPACE® device, in the treatment of diabetic foot ulcers. On December 28, 2017, the FDA determined that the criteria at section 513(a)(1)(A) of (B) of the FD&C Act were met and granted the *de novo* clearance classifying dermaPACE® as Class II and available to be marketed immediately.

Also, our dermaPACE® device 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, Brazil, Mexico, and South Korea.

We are actively marketing the dermaPACE® to the European Community, Canada, Brazil, Mexico, and Asia/Pacific, utilizing distributors in select countries.

Financial Overview

Since inception in 2005, our operations have primarily been funded from the sale of capital stock, notes payable, and convertible debt securities. We expect to devote substantial resources for the commercialization of the dermaPACE® System 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 $27.3 million and $30.9 million for the years ended December 31, 2021 and 2020, respectively. These factors and the events of default on the notes payable create substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the financial statement issuance date.

Our operating losses create substantial doubt about our ability to continue as a going concern. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing may provide the necessary funding for us to continue as a going concern for the next year. See "Liquidity and Capital Resources" for further information regarding our financial condition.

The continuation of our business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2022 and 2023 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or raise capital through the conversion of outstanding warrants, the 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 shareholders. 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. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions 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 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.

Since our inception, we have incurred losses from operations each year. As of December 31, 2021, we had an accumulated deficit of $183.9 million. Although the size and timing of our future operating losses are subject to significant uncertainty, we anticipate that our operating losses will continue over the next few years as we incur expenses related to commercialization of our dermaPACE® system for the treatment of diabetic foot ulcers in the United States. If we are able to successfully commercialize, market and distribute the dermaPACE® system, then we hope to partially or completely offset these losses in the future. Although no assurances can be given, we believe that potential additional issuances of equity, debt or other potential financing, as discussed above, may provide the necessary funding for us to continue as a going concern for the next year.

We cannot reasonably estimate the nature, timing and costs of the efforts necessary to complete the development and approval of, or the period in which material net cash flows are expected to be generated from, any of our products, due to the numerous risks and uncertainties associated with developing and marketing products, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of successful marketing, sales and distribution channels and partnerships, including our efforts to expand our marketing, sales and distribution reach through joint ventures and other contractual arrangements;
- the cost and timing associated with establishing reimbursement for our products;
- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior.

Any failure to complete the development of our product candidates in a timely manner, or any failure to successfully market and commercialize our product candidates, would have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with us and our business are set forth under the section entitled "Risk Factors – Risks Related to Our Business".

The worldwide spread of the COVID-19 virus is expected to result in a global slowdown of economic activity which is likely to decrease demand for a broad variety of products, including from our customers, while also disrupting supply channels and marketing activities for an unknown period of time until the disease is contained. Also, the pandemic may cause continued or additional actions by hospitals and clinics such as limiting elective procedures and treatments and limiting clinical trial activities and data monitoring. We expect all of these factors to have a negative impact on our sales and our results of operations, the size and duration of which we are currently unable to predict.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to the estimate of the fair value of embedded conversion options and warrants. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any future period.

In addition, there are other items within our financial statements that require estimation but are not deemed critical as defined above. Changes in these and other items could still have a material impact upon our financial statements.

The following accounting policies are deemed critical.

Revenue Recognition

We recognize revenue in accordance with two different Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") standards: 1) Topic 606 and 2) Topic 842. In accordance with ASC 606, we apply the following the five-step model: (1) identify the contract(s) with a customer, (2) identify the performance obligation(s) in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when (or as) the Company satisfies a performance obligation. We recognize revenue primarily from the following types of contracts under ASC 606: (1) sales of products, accessories and parts, (2) licensing fees, (3) other revenue, (4) shipping and handling costs. The company also recognizes rental revenue under ASC 842 where we have determined that these are operating leases and we recognize the revenue in the period where it is billed to the customer. However, under the pay per use agreement, the Company will earn revenues based on the number of times the device is used. Under the guidance Lease payments based on usage of the device are variable lease payments and should be recorded in the period in which the obligation for the payment is incurred.

Derivative Liability's from Embedded Conversion Options and Warrants– Under ASC Topic 815 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 under ASC Topic 815 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 of time equal to the remaining life of the instruments.

Results of Operations for the Years ended December 31, 2021 and 2020

The following table sets forth our consolidated statement of operations for the fiscal years ended December 31, 2021 and 2020, and the change between the two years (dollars in thousands):

	For the Years Ended December 31,		Change	
	2021	2020	$	%
Revenues:				
Total Revenue	$ 13,010	$ 4,057	$ 8,953	221%
Cost of Revenues	4,986	1,162	3,824	329%
Gross Margin	8,024	2,895	5,129	177%
Operating Expenses:				
General and administrative	11,690	13,723	(2,033)	-15%
Selling and marketing	8,591	5,160	3,431	66%
Research and development	1,101	1,246	(145)	-12%
Impairment of intangible assets	-	7,185	(7,185)	-100%
Depreciation and amortization	784	781	3	0%
Operating Loss	(14,142)	(25,200)	11,058	-44%
Other Income (Expense), net	(13,089)	(5,737)	(7,352)	128%
Income tax expense	28	-	28	-
Net Loss	$ (27,259)	$ (30,937)	3,678	-12%

Revenues and Cost of Revenues

Revenues for the year ended December 31, 2021 were $13.0 million, compared to $4.1 million for the same period in 2020, an increase of $8.9 million or 221%. Revenue resulted primarily from sales in Europe and Asia/Pacific of our orthoPACE devices and related applicators and sales in the United States and Asia/Pacific of our dermaPACE® devices and related applicators as well as UltraMIST® product sales after the August 6, 2020 Acquisition. The primary driver for the revenue increase were a full year of sales of the UltraMIST® product for the year ended December 31, 2021, as compared to approximately five months of sales totaling $3.7 million for the year ended December 31, 2020.

Cost of revenues for the year ended December 31, 2021 were $5.0 million, compared to $1.2 million for the same period in 2020. The increase in cost of revenues was primarily driven by sales of the UltraMIST® product subsequent to the August 6, 2020 Acquisition. Gross profit as a percentage of revenues was 62% for the year ended December 31, 2021, compared to 71% for the same period in 2020. The decrease in gross profit as a percentage of revenues in 2021 was primarily due the increase in higher margin sales in the third and fourth quarter of 2020 offset by the minimum purchase fee related to the acquisition that was recorded in the first and second quarters of 2021 with no associated revenue.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2021 were $1.1 million, compared to $1.2 million for the same period in 2020, a nominal decrease. The decrease in research and development expenses in 2021, as compared to 2020, was due to contracting expenses for temporary services, increased services related to the dosage study in Poland and increased expenses related to electrical testing for the device as well as the acquisition of additional of employee to support the UltraMIST® products that occurred during the year ended December 31, 2020.

Selling and Marketing Expenses

Selling and marketing expenses for the year ended December 31, 2021 were $8.6 million as compared to $5.2 million for the same period in 2020, an increase of $3.4 million, or 66%. The year-over-year increase in sales and marketing expenses in 2021 was a result of a full year of sales and marketing expenses related to operating the UltraMIST® business compared to approximately five months of UltraMIST® operations as a result of the August 6, 2020 Acquisition.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2021 were $11.7 million as compared to $13.7 million for the same period in 2020, a decrease of $2.0 million, or 15%. The decrease in 2021 as compared to 2020, was primarily due to the higher costs in 2020 resulting from the acquisition-related transaction expenses, share-based compensation for services, higher lease and payroll-related to costs subsequent to the August 6, 2020 Acquisition, as well as increased consulting and IT costs associated with the integration of the Acquisition.

Impairment of Intangible Assets

During the fourth quarter of 2020, the Company determined that the intangible asset for customer relationships related to the biological products was impaired due to significant shortfalls in sales of the products during that period compared with the sales projections used to determine the fair value the intangible asset as of the August 6, 2020 acquisition date. The Company does not expect sales of biological products to sufficiently recover. At December 31, 2020, the Company recorded a $7.2 million impairment charge for this intangible asset. The Company has determined that there is no impairment charge for the year ended December 31, 2021.

Depreciation and Amortization Expenses

Depreciation and amortization operating expenses were $784 thousand for the year ended December 31, 2021 versus $781 thousand for the same period of 2020.

Other Income (Expense)

Other income (expense) was a net expense of $13.1 million for the year ended December 31, 2021, as compared to a net expense of $5.7 million for the same period in 2020, a net expense increase of $7.4 million. The change was driven by increased interest expense of $4.7 million, and a loss on the issuance of debt of $3.6 million, partially offset by the decrease of the change in the fair value of derivative liability of $1.2 million. The increased interest expense was the result of higher levels of debt outstanding during 2021 compared with 2020 and the change in fair value of the derivative liability relates to warrants issued during 2021.

Net Loss

Net loss for the year ended December 31, 2021 was $27.3 million, or ($0.05) per basic and diluted share, compared to a net loss of $30.9 million, or ($0.08) per basic and diluted share, for the same period in 2020. The decrease in the net loss was primarily a result of higher 2021 operating and other expenses, partially offset by increases in revenues/gross margin as noted above.

Liquidity and Capital Resources

As of December 31, 2021, our cash, cash equivalents and marketable securities totaled $.6 million.

We have incurred a net loss of $27.3 million and $30.9 million for the years ended

December 31, 2021 and 2020, respectively and cash used for operating and capital investment in the business was $6.9M We expect to continue to incur substantial negative cash flows from operations for the first half of 2022

Our expected cash requirements for the next 12 months and beyond are largely based on the commercial success of our products and the level of targeted investment in our commercial strategies. These conditions as well as the events of default on various notes payable raise substantial doubt about our ability to continue as a going concern.

We have historically funded our operations from the sale of our common stock, issuance of notes payable, and the exercise of warrants. During the year ended December 31, 2021, we received net proceeds of approximately $5.1 million net from such activities, and as of December 31, 2021, our cash, cash equivalents and marketable securities totaled $.6 million.

The company has material cash requirement in 2022 including past due payables, contract obligations to our critical vendors, notes in default, registration and other penalties related to notes payable, warrants, and registration right agreements. Management's plans to address the short-term and liquidity needs are to obtain additional capital in 2022 and 2023 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or 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 shareholders. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions 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.

Beyond the next 12 months, we expect to devote substantial resources for the commercialization of the dermaPACE® System and will continue to research and develop the next generation of our technology as well as the non-medical uses of the PACE technology, both of

which will require additional capital resources. We also plan to devote resources to the continued commercialization of the dermaPACE and UltraMIST® product including hiring of new employees, expansion of our international business and continued research and development of next generation of our technology as well as non-medical uses of our technology

Our existing resources are unlikely to allow us to conduct all the activities that we believe could be beneficial for our future growth. As a result, we will need to seek additional funds in the future or curtail or forgo some or all such activities. If we seek to and are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Changes, including those relating to the payer and competitive landscape, our commercialization strategy, our development activities and regulatory matters, may occur beyond our control that would cause us to consume our available capital more quickly.

Master Equipment Lease

On January 26, 2018, the Company entered into a Master Equipment Lease with NFS Leasing Inc. ("NFS") to provide financing for equipment purchases to enable the Company to begin placing the dermaPACE® System in the marketplace. This agreement provides for a lease line of up to $1,000,000 with a term of 36 months, and grants NFS a security interest in the Company's accounts receivable, tangible and intangible personal property and cash and deposit accounts of the Company. In 2020 and 2021, the Company entered into additional equipment leases under the Master Equipment Lease and they are included in property, plant and equipment as a right of use asset with a related finance lease liability in our consolidated balance sheets.

Series C convertible preferred stock certificate of designation

On January 31, 2020, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series C Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 90 shares of our preferred stock as Series C Convertible Preferred Stock. Although we have no other shares of preferred stock currently outstanding and no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

Convertible notes payable

On August 6, 2020, the Company entered into a letter agreement (the "HealthTronics Agreement") with HealthTronics pursuant to which the Company paid off all outstanding debt due and owed to HealthTronics, including the notes payable. Pursuant to the HealthTronics Agreement, as consideration for the extinguishment of the debt due to HealthTronics, (i) the Company paid to HealthTronics an amount in cash equal to $4.0 million, (ii) HealthTronics exercised all of its outstanding Class K Warrants to purchase 7,200,000 shares of common stock, (iii) the Company issued to HealthTronics a convertible note payable in the amount of $1.4 million, and (iv) the Company and HealthTronics entered into a Securities Purchase Agreement dated August 6, 2020 pursuant to which the Company issued to HealthTronics an aggregate of 8,275,235 shares of common stock and an accompanying Class E warrant to purchase up to an additional 8,275,235 shares of common stock. The warrant has an exercise price of $0.25 per share and a three-year term.

The convertible promissory note, with principal amount of $1.4 million, matured on August 6, 2021 and has not been repaid. The Company's failure to pay the outstanding principal balance when due constituted an event of default under the terms of the convertible note payable and, accordingly, it began accruing interest of 2% in addition to the 12% initial rate as of the date of the default.

In the event that the Seller Note has not been repaid prior to January 1, 2021, HealthTronics may elect to convert the outstanding principal amount plus any accrued but unpaid interest thereon into shares of the Company's common stock, at a conversion price of $0.10 per share. As this conversion option is contingent, the conversion option has not been bifurcated from the host instrument as of December 31, 2020. The convertible promissory note is expressly subordinate to the NWPSA "Senior Secured Notes" described in Note 13. The Company may prepay the outstanding principal balance, together with any accrued but unpaid interest without premium or penalty.

SBA loans

On May 28, 2020, the Company received proceeds from a loan in the amount of $454 thousand (the "PPP Loan") from Truist Bank, as lender, pursuant to the Paycheck Protection Program ("PPP") under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The PPP Loan matures on May 28, 2022 and bears interest at a rate of 1% per annum. Commencing December 12, 2020, the Company is required to pay the lender equal monthly payments of principal and interest. The PPP Loan is evidenced by a promissory note dated May 28, 2020 (the "Note"), which contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties and covenants. The PPP Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties.

All or a portion of the PPP Loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application by the Company beginning 60 days but not later than 120 days after loan approval and upon documentation of expenditures in accordance with the SBA requirements. The ultimate forgiveness of the PPP Loan is also predicated upon regulatory authorities concurring with management's good faith assessment that the current economic uncertainty made the loan request necessary to support ongoing operations. If, despite the Company's good-faith belief that given the circumstances the Company satisfied all eligibility requirements for the PPP Loan, the Company is later determined to have violated any applicable laws or regulations or it is otherwise determined that the Company was ineligible to receive the PPP Loan, the Company may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties. In the event the PPP Loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal. Under the terms of the PPP Loan, the Company may be eligible for full or partial loan forgiveness in the third quarter of 2020. The Company completed the application for loan forgiveness during the third quarter of 2021. The Company received a letter from the SBA dated August 27, 2021 forgiving $454 thousand of the PPP Loan principal and $6 thousand of interest.

On June 10, 2020, the Company secured a loan offered by the U.S. Small Business Administration ("SBA") under its Economic Injury Disaster Loan assistance program ("EIDL") in light of the impact of COVID-19 pandemic on the Company's business. The principal amount of this loan was $150 thousand and interest accrued at the rate of 3.75% per annum. This loan was repaid in full on August 5, 2020 with proceeds from the NWPSA Senior Notes as part of the conditions of that agreement.

Senior Secured promissory notes

On August 6, 2020, the Company entered into a Note and Warrant Purchase and Security Agreement (the "NWPSA"), with the noteholder party thereto and NH Expansion Credit Fund Holdings LP, as agent. As a result, the Company issued a $15,000,000 Secured Promissory Note (the "Senior Notes") and Warrant exercisable into shares of the Company's common stock (the "Warrant") in exchange for cash to support operations, repay outstanding debt and close on the acquisition of the UltraMIST® assets from Celularity, among other transactions. The Company received net proceeds from issuing the Notes and NH Warrant of $13.3 million. The NWPSA provides for (i) the sale and purchase of secured notes in an aggregate original principal amount of $15 million and (ii) the issuance of 13,091,160 warrants equal to 2.0% of the fully-diluted common stock of the Company as of the issue date. The warrant has an exercise price of $0.01 per share and a 10-year term. The warrant agreement contains a put option. Upon payment in full of the Note, the holder has the ability to require the Company to purchase the warrants from the holder for cash. Accordingly, the warrant has been classified as a derivative liability. The holder has the option to exercise the put any time between the payment of the Note and the expiration of the warrants. The Note has a maturity date of September 30, 2025 and accrues interest at a rate that is the sum of: (a) the greater of the quarter end prime rate or 3% plus (b) 9%, due in quarterly arrears. The Senior Notes are secured by substantially all assets of the Company including in the event of default placing bank accounts under a control agreement, copyrights, trademarks, patents, applications, registered and unregistered, licenses, designs, held or acquired after August 6, 2020 by the Company.

The Company was in default of the minimum liquidity provisions of the Senior Secured Promissory Notes beginning in October 2020 and, accordingly, the Senior Promissory Notes began accruing interest of 5.0% in addition to the stated rate as of the date of default.

Convertible promissory notes – 2020

On August 6, 2020, the Company entered into an asset purchase agreement with Celularity, pursuant to which the Company acquired Celularity's UltraMIST® assets. A portion of the aggregate consideration of $24.0 million paid for the assets included the issuance of a promissory note to Celularity in the principal amount of $4.0 million. The Seller Note had a maturity date of 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 default.

In the event that the Seller Note had not been repaid prior to January 1, 2021, Celularity may elect to convert the outstanding principal amount plus any accrued but unpaid interest thereon into shares of the Company's common stock, at a conversion price of $0.10 per share. As this conversion option is contingent on a future event, the conversion option has not been bifurcated from the host instrument as of December 31, 2020. The Seller Note is expressly subordinate to the NWPSA Senior Notes described above under "Senior Secured Promissory Notes." The Company may prepay the outstanding principal balance, together with any accrued but unpaid interest without premium or penalty.

On June 5, 2020, the Company entered into a Securities Purchase Agreement with investor LGH Investments LLC (the "Investor") for (i) a Promissory Note (the "Convertible Promissory Note") in the original principal amount of $1.2 million, convertible into shares of common stock, (ii) warrants entitling the Investor to acquire 1,075,000 shares of common stock (the "Warrants") and (iii) 200,000 restricted common shares in the Company as an inducement grant (the "Inducement Shares"). Such note contained certain default provisions, as defined, resulting in net proceeds of $1.1 million. As part of the Securities Purchase Agreement, the Company established a reserve of shares of its authorized but unissued and unreserved common stock in the amount of 11,000,000 shares for purposes of exercise of the Warrant or conversion of the Convertible Promissory Note. The Convertible Promissory Note matures on February 5, 2021 and includes a one-time interest charge of 8% to be applied on the issuance date to the original principal amount. The Investor can convert the Convertible Promissory Note and interest at any time prior to maturity to the number of shares of common stock, equal to the amount obtained by dividing (i) the amount of the unpaid principal and interest on the note by (ii) $0.25. The Warrants have an exercise price of $0.35 per share and have a term of five years and recorded as a liability by the Company. With respect to the Inducement Shares, in the event the Company's share price has declined on the date on which the Investor seeks to have the restricted legend removed on such shares, the Company agrees to issue the Investor additional shares such that the aggregate value of the Inducement Shares equals the aggregate value of the Inducement Shares as of June 5, 2020. The Inducement Shares were issued on September 11, 2020 and included in common stock and additional paid in capital.

We may also attempt to raise additional capital if there are favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. To the extent that we raise additional funds by issuance of equity securities, our shareholders will experience dilution and we may be required to use some or all of the net proceeds to repay our indebtedness, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones would harm our future capital position.

April 2021 Securities Purchase Agreement and Warrants

On April 20, 2021, the Company entered into a Securities Purchase Agreement (the "Leviston Purchase Agreement"), with Leviston Resources, LLC, an accredited investor ("Leviston") for the sale by the Company in a private placement (the "Private Placement") of (i) the Company's future advance convertible promissory note in an aggregate principal amount of up to $3.4 million (the "Leviston Note") and (ii) a warrant to purchase an additional 16,666,667 shares of common stock of the Company (the "Leviston Warrant"). The Leviston Warrant has an exercise price of $0.18 per share and a four-year term. The closing of the Private Placement occurred on April 20, 2021 (the "Leviston Closing Date").

As noted above, on April 20, 2021, the Company issued the Leviston Note to the Purchaser in an aggregate principal amount of up to $3.4 million (the "Aggregate Amount"), which shall be advanced in disbursements by the Purchaser ("Leviston Disbursements"), as set forth in the Leviston Note. On May 14, 2021, the Leviston Note was amended to increase the Aggregate Amount to $4.2 million. On April 21, 2021, the Purchaser advanced a Leviston Disbursement of $750 thousand, which is net of an original issue discount of 8%. On May 14, 2021, the Purchaser advanced a second Leviston Disbursement of $750 thousand, also net of an original issue discount of 8%. A $250 thousand Leviston Disbursement was made on September 3, 2021, which was subject to the same terms and conditions of the April and May Leviston Disbursements. In addition, a $500 thousand disbursement was made on September 3, 2021 in accordance with notes issued to five institutional investors (the "Five Institutions' Notes"), which were subject to substantially the same terms and conditions as the Leviston Disbursements.

Cash flows (uses) from operating, investing and financing activities - For the years ended December 31, 2021 and 2020, net cash used by operating activities was $6.4 million and $12.7 million, respectively, primarily consisting of compensation costs, research and development activities and general corporate operations. The decrease in the use of cash for operating activities for the year ended December 31, 2021, as compared to the same period for 2020, of $6.1 million, or 47%, was primarily due to the decrease in the net loss, a decrease in accounts receivable, as well as decreases in accrued interest, and interest payable, related parties, partially offset by increases in certain non-cash expenses, such as depreciation and amortization, bad debt expense, amortization of debt issuance costs and original issue discount, and change in fair value of derivative liability and increases in accounts payable and accrued expenses.

Net cash used by investing activities in 2021 was $529 thousand as compared to net cash used by investing activities of $20.1 million in 2020. The decrease is primarily due to the $20,000,000 Acquisition of UltraMIST® on August 6, 2020.

Net cash provided by financing activities for the year ended December 31, 2021 was $5.1 million, which consisted of proceeds from convertible promissory notes of $1.9 million, cash received from accounts receivable factoring of $1.7 million, proceeds from notes payable of $940 thousand, less principal payments of $436 thousand on debt and finance lease obligations. Net cash provided by financing activities for the year ended December 31, 2020 was $33.4 million, which consisted of proceeds from PIPE offerings of $21.4 million, proceeds from notes payable of $13.3 million, advances from related parties of $23 thousand, net proceeds from sales of convertible preferred stock and convertible promissory notes totaling $3.6 million, proceeds from SBA loans of $614 thousand, and proceeds from exercises of stock options and warrants totaling $48 thousand, less principal payments totaling $5.6 million on debt and finance lease obligations.

Cash and cash equivalents decreased by $1.8 million for the year ended December 31, 2021 and cash and cash equivalents increased by about $676 thousand for the year ended December 31, 2020.

Contractual Obligations

Our major outstanding contractual obligations relate to operating leases for our two facilities and office equipment, as well purchase and supplier obligations for product component materials and equipment, and our notes payable, related parties.

In August 2016, we entered into a lease agreement for 7,500 square feet of office space for office, research and development, quality control, production and warehouse space which expired on December 31, 2021. On February 1, 2018, we entered into an amendment to the lease agreement for an additional 380 square feet of office space for storage which expired on December 31, 2021. On January 2, 2019, we entered into a second amendment to the lease agreement for an additional 2,297 square feet of office space for office space which expired on December 31, 2021. Under the terms of the lease, we pay monthly rent of $14,651, subject to a 3% adjustment on an annual basis.

As part of its August 6, 2020 Acquisition, we became party to a lease agreement for 8,199 square feet of office space for office, research and development, quality control, and warehouse space which expires on August 31, 2023. Under the terms of the lease, the Company pays monthly rent of $7,051, with escalation of approximately 2% on May 1 of each lease year.

Also on August 6, 2020, the Company became party to a lease for office equipment that requires monthly payments of $669 through May 31, 2025.

We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantities of product component materials for our products through the development, clinical testing and commercialization phases. We have a manufacturing supply agreement with Swisstronics Contract Manufacturing AG in Switzerland, a division of Cicor Technologies Ltd., covering the generator box component of our PACE devices. We have a manufacturing supply agreement with Minnetronix for the UltraMIST® devices and the Dynamic Group for UltraMIST® applicators. Celularity is our current supplier of the Biovance and Interfyl product lines. See Note 25, Subsequent Events, for information regarding disputes with Celularity and Minnetronix.

On August 6, 2020 the Company assumed obligations for a purchase order for UltraMIST® devices from Celularity related to purchases of UltraMIST® devices from Minnetronix. This purchase order had a remaining purchase commitment of $1,058,170. This purchase agreement also calls for production delay fees of 1.25% of the committed inventory if the Company delays production. There is also a cancelation clause of 20% of the remaining balance in the event that the Company delays production for more than six months. For additional details, see “Contingencies” in Note 20 of the Notes to Consolidated Financial Statements.

Recently Issued Accounting Standards

New accounting pronouncements are issued by the Financial Standards Board (“FASB”) or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies. The Company does not expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company’s results of operations, financial position or cash flow. See Note 3 to the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Effects of Inflation

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required under Regulation S-K for “smaller reporting companies”.

Item 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2021 and 2020, the related consolidated statements of comprehensive loss, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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 significant 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

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

/s/ Marcum LLP
Marcum LLP

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

New York, NY
May 13, 2022

PART I -- FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2021 and 2020
(In thousands except share data)

	2021	2020
ASSETS		
Current Assets:		
Cash	$ 619	$ 2,437
Accounts receivable, net of allowance for doubtful accounts of $785 in 2021 and $343 in 2020	2,415	2,356
Inventory	1,040	2,956
Prepaid expenses and other current assets	326	179
Total Current Assets	4,400	7,928
Property and Equipment, net	668	471
Right of Use Assets, net	344	795
Other Intangible Assets, net	5,841	6,545
Goodwill	7,260	7,260
Other Assets	106	28
Total Assets	$ 18,619	$ 23,027
LIABILITIES		
Current Liabilities:		
Senior secured promissory note payable, in default	$ 11,586	$ 10,676
Convertible promissory notes payable, in default	11,601	4,000
Convertible promissory notes, related parties, in default	1,596	1,596
Advances on future cash receipts	446	-
Accounts payable	7,644	4,454
Accrued expenses	4,394	2,127
Accrued employee compensation	4,247	2,541
Due under factoring agreement	1,737	-
Warrant liability	9,614	8,855
Current portion of SBA loans	158	321
Accrued interest	2,521	1,021
Accrued interest, related parties	289	77
Current portion of lease liabilities	268	451
Current portion of contract liabilities	48	32
Other	114	23
Total Current Liabilities	56,263	36,174
Non-current Liabilities		
SBA loans	875	143
Lease liabilities	118	391
Contract liabilities	293	37
Deferred tax liability	28	-
Total Non-current Liabilities	1,314	571
Total Liabilities	57,577	36,745
Commitments and Contingencies (Footnote 19)		
STOCKHOLDERS' DEFICIT		
Preferred Stock, par value $0.001, 5,000,000 shares authorized; 6,175, 293, 90 and 8 shares designated Series A, Series B, Series C and Series D, respectively; no shares issued and outstanding at December 31, 2021 and 2020	-	-

Common Stock, par value $0.001, 800,000,000 shares authorized; 481,619,621 and 470,694,621 issued and outstanding at December 31, 2021 and 2020, respectively	482	471
Additional Paid-in Capital	144,582	142,563
Accumulated Deficit	(183,949)	(156,690)
Accumulated Other Comprehensive Loss	(73)	(62)
Total Stockholders' Deficit	(38,958)	(13,718)
Total Liabilities and Stockholders' Deficit	$ 18,619	$ 23,027

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, 2021 and 2020
(In thousands except share data)

	2021	2020
Revenues:		
Accessory and parts revenue	$ 8,072	$ 1,209
Product	3,116	2,267
Rental income	1,627	429
License fees and other	195	152
Total Revenue	13,010	4,057
Cost of Revenues	4,986	1,162
Gross Margin	8,024	2,895
Operating Expenses:		
General and administrative	11,690	13,723
Selling and marketing	8,591	5,160
Research and development	1,101	1,246
Impairment of intangible assets	-	7,185
Depreciation and amortization	784	781
Total Operating Expenses	22,166	28,095
Operating Loss	(14,142)	(25,200)
Other Income (Expense):		
Interest expense	(6,883)	(2,025)
Interest expense, related party	(212)	(516)
Partnership fee income	-	600
Change in fair value of derivative liabilities	(2,622)	(3,193)
Loss on issuance of debt	(3,572)	-
Gain / (loss) on extinguishment of debt	204	(565)
Gain / (loss) on foreign currency exchange	(4)	(38)
Other Income (Expense), net	(13,089)	(5,737)
Net Loss before Income Taxes	(27,231)	(30,937)
Income tax expense	28	-
Net Loss	(27,259)	(30,937)
Other Comprehensive Loss		
Foreign currency translation adjustments	(11)	-
Total Comprehensive Loss	$ (27,270)	$ (30,937)
Loss per Share:		
Net loss per share, basic and diluted	$ (0.05)	$ (0.08)
Weighted average shares outstanding, basic and diluted	518,355,642	378,128,645

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

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

	Preferred Stock		Common Stock				Acc
	Number of Shares Issued and Outstanding	Par Value	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Com
Balances as of December 31, 2019	-	$ -	293,780,400	$ 294	$ 115,458	$ (125,753)	$
Net loss	-	-	-	-	-	(30,937)	
Proceeds from warrant exercise	-	-	1,000,000	1	9	-	
Conversion of short term notes and convertible notes payable	-	-	4,829,789	5	560	-	
Reclassification of warrant liability to equity	-	-	-	-	6,293	-	
Conversion of advances from related parties	-	-	262,811	-	18	-	
Conversion of notes payable, related parties	-	-	15,475,235	15	2,276	-	
Shares issued for services	-	-	12,700,000	13	2,533	-	
Proceeds from PIPE offering, net of offering costs	-	-	124,621,428	125	12,558	-	
Stock-based compensation	-	-	-	-	22	-	
Proceeds from stock option exercise	-	-	325,000	-	48	-	
Beneficial conversion feature on convertible debt	-	-	-	-	561	-	
LGH warrant liability	-	-	-	-	(249)	-	
Series C and Series D preferred stock converted to common stock	-	-	17,499,958	18	2,432	-	
Inducement shares issued	-	-	200,000	-	44	-	
Foreign currency translation adjustment	-	-	-	-	-	-	
Balances as of December 31, 2020	-	$ -	470,694,621	$ 471	$ 142,563	$ (156,690)	$
Cashless warrant exercise	-	-	10,925,000	11	(11)	-	
Reclassification of warrant liability due to cashless warrant exercise	-	-	-	-	2,030	-	
Net loss	-	-	-	-	-	(27,259)	
Foreign currency translation adjustment	-	-	-	-	-	-	
Balances as of December 31, 2021	-	$ -	481,619,621	$ 482	$ 144,582	$ (183,949)	$

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2021 and 2020
(In thousands)

	2021	2020
Cash Flows - Operating Activities:		
Net loss	$ (27,259)	$ (30,937)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization of intangibles	704	713
Depreciation	532	299
Bad debt expense	442	302
Impairment of intangible assets	-	7,185
Stock-based compensation	-	22
Shares issued for services	-	2,546
Shares issued for inducement	-	45
Gain/loss on extinguishment of debt	(204)	565
Income tax expense	28	-
Change in fair value of derivative liabilities	2,622	3,193
Loss on issuance of debt	3,572	-
Amortization of debt issuance costs and original issue discount	3,226	484
Accrued interest	1,506	1,098
Interest payable, related parties	212	401
Changes in operating assets and liabilities		
Accounts receivable - trade	(395)	(2,582)
Inventory	1,916	(553)
Prepaid expenses	(118)	(54)
Other assets	(111)	13
Operating leases	-	(6)
Accounts payable	3,181	3,015
Accrued expenses	1,818	1,169
Accrued employee compensation	1,837	934
Contract liabilties	82	(570)
Net Cash Used by Operating Activities	(6,409)	(12,718)
Cash Flows - Investing Activities		
Acquisition of UltraMIST, net of $4,000,000 note payable to seller	-	(20,000)
Purchases of property and equipment	(529)	(53)
Net Cash Flows Used by Investing Activities	(529)	(20,053)
Cash Flows - Financing Activities		
Proceeds from sale of convertible preferred stock	-	2,450
Proceeds from convertible promissory notes	1,928	1,100
Proceeds from SBA loan	1,033	614
Proceeds from PIPE offering, net of offering costs	-	21,456
Proceeds from senior secured promissory notes	940	13,347
Proceeds from stock option exercises	-	48
Proceeds from factoring	1,737	-
Proceeds from warrant exercises	-	10
Advances from related parties	175	23
Repayments of debt principal on convertible promissory notes, related parties, convertible promissory notes and SBA loans	(493)	(5,458)
Payments of principal on finance leases	(199)	(143)
Net Cash Flows Provided by Financing Activities	5,121	33,447
Effect of Exchange Rates on Cash	(1)	-

Net Change in Cash During Period	(1,818)	676
Cash at Beginning of Period	2,437	1,761
Cash at End of Period	$ 619	$ 2,437
Supplemental Information:		
Cash paid for interest	$ 2,580	$ 436
Non-cash Investing and Financing Activities:		
Reclassification of warrant liabilities to equity	$ 2,030	$ 6,293
Embedded conversion feature on convertible debt	4,138	561
Warrant issuance in conjunction with advances on future cash receipts	1,227	-
Warrant issuance in conjunction with convertible notes	1,055	-
Acquisition of UltraMIST partially financed with convertible promissory note	-	4,000
Conversion of notes payable, related parties	-	2,291
Series C and Series D preferred stock converted to common stock	-	2,450
Exchange line of credit and notes payable, related parties, for convertible promissory notes, related partes	-	1,596
Conversion of short-term notes payable to equity	-	565
Conversion of advance from related parties	-	18

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

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2021 and 2020

1. Nature of the Business and Basis of Presentation

SANUWAVE Health, Inc. and Subsidiaries ("SANUWAVE" or the "Company") is focused on the research, development, and commercialization of its patented noninvasive and biological response activating medical systems for the repair and regeneration of skin, musculoskeletal tissue, and vascular structures. The Company's lead regenerative product in the United States is the dermaPACE® device used for treating diabetic foot ulcers.

Through the Company's acquisition, on August 6, 2020, of the UltraMIST® assets from Celularity, Inc. ("Celularity"), SANUWAVE now combines two highly complementary and market-cleared energy transfer technologies and two human tissue biologic products, which creates a platform of scale with an end-to-end product offering in the advanced wound care market.

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.

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. Accrued executive severance at December 31, 2020 of $154 thousand was reclassified from accrued expenses to accrued employee compensation. This reclassification had no effect on the previously reported operating results.

COVID-19 **–** The worldwide spread of the COVID-19 virus resulted in a global slowdown of economic activity which is likely to decrease demand for a broad variety of products, including from our customers. We have experienced a disruption of our supply channels which will continue for an unknown period of time until the global supply chain can return to the pre- disease status. Also, the pandemic may cause 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 and we expect that they will continue to have a negative impact on our sales and our results of operations, the size and duration of which we are currently unable to predict.

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 commercialization of the dermaPACE and will continue to research and develop the non-medical uses of the PACE technology, both of 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 Form 10-K.

The continuation of our business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2022 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or 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 shareholders. 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. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions 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. 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, useful lives of long-lived assets, fair value of goodwill and other 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.

Cash - The Company maintains its cash in bank accounts which may exceed federally insured limits.

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.

Concentration of credit risk - Management routinely assesses the financial strength of its customers and, as a consequence, 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 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.

Property and equipment **–** Property and equipment is recorded at cost, net of accumulated depreciation. The costs of additions and betterments are capitalized and expenditures for repairs and maintenance, which do not extend the economic useful life of the related assets, are expensed. The straight-line method of depreciation is used for computing depreciation on property and equipment over the following estimated useful lives:

	Estimated Useful Life
Machines and equipment	3 years
Office and computer equipment	3 years
Medical devices on rent	5 - 15 years
Software	2years
Furniture and fixtures	3 years

Goodwill and Other Intangible Assets **—** Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company accounts for goodwill under ASC Topic 350, *Intangibles-Goodwill and Other*. The Company tests goodwill for impairment annually, or more frequently whenever events or circumstances indicate impairment may exist. Goodwill is stated at cost less 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 for the year ended December 31, 2021. 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. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The Company has determined that there were no impairment to goodwill or intangible assets for the year ended December 31, 2021.

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. Except for the impairment of the intangible assets discussed above, the Company determined that no impairment of long-lived assets was indicated at December 31, 2021.

Leases **–** We determine whether an arrangement is a lease at inception. When our lease arrangements include lease and non-lease components, we account 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 sheet, and we recognize 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 our right of use assets and lease liabilities. None of our lease agreements include an option to purchase the leased asset, residual value guarantees, or material restrictive covenants.

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.

Preferred stock – The Company evaluates preferred stock issuances for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determines appropriate equity or liability accounting treatment. Additionally, the Company determines, if classified as equity, whether it would be recorded as permanent or temporary equity.

Sequencing policy – The Company follows 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 on the basis of earliest issuance date of potentially dilutive instruments with the earliest grants receiving first allocation of shares.

Convertible instruments and liabilities related to warrants issued – 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 ("ECOs") 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 as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. A binomial model was used to estimate the fair value of the ECOs of warrants 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. The expected volatility is estimated based on the actual volatility during the most recent historical period of time equal to the weighted average life of the instruments.

Warrants related to debt issued – The Company records a warrant 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 warrant discount is reported as a reduction of the related debt liability.

Beneficial conversion feature on convertible debt - The Company records a beneficial conversion feature related convertible 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 in the accompanying Consolidated Statements of Comprehensive Loss. This beneficial conversion feature is reported as a reduction of the related debt liability in the accompanying Consolidated Balance Sheet.

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

Revenue Recognition – We recognize revenue in accordance with two different Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") standards: 1) Topic 606 and 2) Topic 842.

Topic 606

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. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under previous U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In accordance with ASC 606, we apply the following the five-step model:

1. Identify the contract(s) with a customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

2. Identify the performance obligation(s) in the contract. If a contract promises to transfer more than one good or service to a customer, each good or service constitutes a separate performance obligation if the good or service is distinct or capable of being distinct.

3. Determine the transaction price. The transaction price is the amount of consideration to which we expect to be entitled in exchanging the promised goods or services to the customer.

4. Allocate the transaction price to the performance obligations in the contract. For a contract that has more than one performance obligation, we allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which we expect to be entitled in exchange for satisfying each performance obligation.

5. Recognize revenue when (or as) the Company satisfies a performance obligation. For each performance obligation, we determine whether we satisfy the performance obligation at a point in time or over time. Appropriate methods of measuring progress include output methods and input methods.

The Company recognizes revenue primarily from the following types of contracts under ASC 606:

Product Sales and Accessory and Part Sales - Product sales and 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. Device product sales are bundled with an initial one-year warranty and the Company offers a separately priced second-year warranty. The Company allocates the device sales price to the product and the embedded warranty by reference to the stand-alone extended warranty price. Because the warranty represents a stand-ready obligation, revenue is recognized over the time period 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.

Topic 842
The Company recognizes revenue primarily from the following types of contracts under ASC 842:

Rental and Pay per Use Income - Rental revenue represents revenues earned from renting equipment either on a monthly basis or on a pay per use. We account for these rental contracts as operating leases and revenue will be recognized on a straight-line basis in the period billed to the customer. However, under the pay per use agreement, the Company will earn revenues based on the number of times the device is used.

The lease terms are included in our contracts, and the determination of whether our contracts contain leases generally does not require significant assumptions or judgments. In some cases, a rental contract may contain a rental purchase option, whereby the customer has an option to purchase the rented equipment at the end of the term for a specified price. Revenues related to the rental contract will be accounted for as an operating lease as the option to purchase is not reasonably certain to be exercised. Lessees do not provide residual value guarantees on rented equipment.

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs incurred have been recorded in cost of revenues.

Research and development - Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to the Company's products in clinical development, such as payments to contract research organizations, consulting fees for FDA submissions, universities performing non-medical related research and insurance premiums for clinical studies and non-medical research. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the clinical affairs, and research and development departments are classified as research and development costs.

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 August 2020, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity,* which simplifies the accounting for convertible instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature and simplifies the guidance for determining whether a conversion feature is a derivative. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost. These changes will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that was bifurcated according to previously existing rules. In addition, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will be no longer available. The new guidance is effective for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. Effective January 1, 2021, the Company elected to early adopt ASU 2020-06 using the modified retrospective method. The adoption of ASU 2020-06 had no impact on the Company's previously reported financial position or operating results.

In June 2016, the FASB issued 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, which will result 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.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes in several areas including calculating taxes in an interim period, clarifying how to account for taxes that are partially based on income and requiring an entity to reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. This amendment is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company adopted ASU 2019-12 effective January 1, 2021 with no impact on previously reported financial position or operating results.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment. The amendments in ASU 2017-04 modified the testing that an entity should perform for its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. This amendment is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2017-04 effective January 1, 2021. The adoption of this guidance did not impact our results of operations or financial position.

In May 2021, the FASB issued Accounting Standards Update ("*ASU*") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40).* This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for us on January 1, 2022. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the effect the adoption of this ASU will have on our consolidated financial statements.

4. 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, 2021 and 2020. 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:

	2021	2020
Weighted average shares outstanding		
Common shares	481,619,621	359,880,132
Common shares issuable assuming excercise of nominally priced warrants	36,736,021	18,248,513
Weighted average shares outstanding	518,355,642	378,128,645

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, 2021 and 2020, 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 at December 31, 2021 and 2020, respectively (dollars in thousands):

	2021	2020
Common stock options	31,760	31,938
Common stock purchase warrants	168,192	142,266
Convertible notes payable	90,380	58,657
	290,332	232,861

5. Asset Purchase Agreement

On August 6, 2020, the Company completed an asset purchase agreement (the "Asset Purchase Agreement") with Celularity pursuant to which the Company acquired (the "Transaction") Celularity's UltraMIST® assets ("UltraMIST®", or the "Assets"). The acquisition provides the Company with a robust product offering in the advanced wound care market and gives the Company an end-to-end advanced wound care product portfolio that addresses the entire care pathway. The aggregate consideration paid for the Assets was $24.0 million, which consisted of (i) a cash payment of $18.9 million, (ii) the issuance of a convertible promissory note to Celularity in the principal amount of $4.0 million (the "Seller Note"), and (iii) a credit of $1.1 million for the previous payment made by the Company to Celularity pursuant to that certain letter of intent between the Company and Celularity dated June 7, 2020.

In connection with the Asset Purchase Agreement, on August 6, 2020, we entered into a license and marketing agreement with Celularity pursuant to which Celularity granted to the Company a license to the Celularity wound care biologic products, Biovance® and Interfyl® (the "License Agreement"). The License Agreement provides the Company with an exclusive license to use, market, distribute and sell Biovance® in the field and territory, as defined in the License Agreement, and a non-exclusive license to use, market, distribute and sell Interfyl® in the field and in the territory. The License Agreement has an initial five-year term, after which it automatically renews for additional one-year periods, unless either party provides written notice at least 180 days prior to the expiration of the current term. The license agreement calls for prepaid minimum quarterly upfront royalty of $446 thousand of payments for Biovance which are credited against sales in that quarter. At December 31, 2021 and 2020 the Company had accrued $893 thousand and $336 thousand of license fees, respectively. Royalties are based on a transfer price for each Biovance product and sales are reported on a quarterly basis to Celularity. In the event of sales in excess of the quarterly minimums, any additional royalties are due at that time.

The Company evaluated the transaction and has accounted for it as a business combination and applied the related accounting guidance as required, using the acquisition method and a fair value model.

The tables below present the consideration paid to Celularity and the fair value of the Assets acquired on August 6, 2020 (dollars in thousands):

Purchase Consideration		
Cash paid at closing	$	18.9
Cash paid pursuant to letter of intent		1.1
Note payable to seller		4.0
Total Consideration	$	24.0

Fair Value of Net Assets Acquired		
Inventory	$	1.9
Property and equipment		0.4
Intangible assets (1)		14.4
Goodwill (2)		7.3
Total fair value of net assets acquired	$	24.0

1. Intangible assets, as summarized below, are recorded at their estimated fair value. The estimated fair value of the acquired customer relationships is determined using the multi-period excess earnings method. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The estimated fair value of the acquired patent and trade names is based on a relief from royalty method. The estimated useful lives for intangible assets were determined based on the remaining useful economic lives of the intangible assets that are expected to contribute directly or indirectly to future cash flows.

2. Goodwill represents the excess of the total purchase consideration over fair value of the assets recognized and represents the future economic benefits that we believe will result from combining the operations of SANUWAVE and UltraMIST®, including expected future synergies and operating efficiencies. Goodwill resulting from the Transaction has been assigned to the Company's lone operating segment. Goodwill is not subject to amortization and is tested for impairment annually and whenever events or changes in circumstances indicate that impairment may have occurred. The goodwill recognized is expected to be deductible for income tax purposes (dollars in thousands).

Intantible Assets	**Fair Value**	**Useful Life (Years)**
Customer relationships - UltraMIST®	$ 3.8	7
Customer relationahips - Biologics	7.6	7
Patent	2.3	19
Trade names	0.7	19
Total intangible assets	$ 14.4	

Acquisition and related costs **-** During the year ended December 31, 2020, acquisition costs of $1.1 million were expensed as incurred and included in general and administrative expenses in the consolidated statements of comprehensive loss. Such costs include professional fees of advisors and integration and synergy costs related to the combination of UltraMIST® and SANUWAVE.

Pro forma impact of acquisition – The table below shows summarized unaudited pro forma combined operating results of the Company for the year ended December 31, 2020 as if the UltraMIST® business acquisition had occurred on the same terms as of January 1, 2020. Pro forma adjustments have been made related to amortization of intangibles, interest expense, and income tax expense for the year ended December 31, 2020. The pro forma financial information does not reflect revenue opportunities and cost savings which the Company expected to realize as a result of the acquisition or estimates of charges related to the integration activity.

	Year Ended December 31 (unaudited)
	2020
Total revenues	$ 7.8
Net Loss	(35.6)

The unaudited pro forma combined results of operations were prepared using the acquisition method of accounting and are based on the historical financial operating results of the Company and UltraMIST®. Except to the extent realized in the year ended December 31, 2020, the unaudited pro forma information does not reflect any cost savings, operating synergies and other benefits that the Company may achieve as a result of the acquisition, or the expenses to be incurred to achieve these savings, operating synergies and other benefits. In addition, except to the extent recognized in the years ended December 31, 2020, the unaudited pro forma information does not reflect the costs to integrate the operations of UltraMIST® within the Company.

The acquired Assets were consolidated into our financial statements starting on the acquisition date. The total revenues and operating income of UltraMIST® consolidated into our financial statements since the date of acquisition through December 31, 2020 were $3.6 million and $467 thousand.

6. Inventory

Inventory consists of the following at December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Inventory - finished goods	$ 335	$ 1,146
Inventory - parts and accessories	705	1,810
Total inventory	$ 1,040	$ 2,956

7. Property and Equipment

Property and equipment consists of the following at December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Machines and equipment	$ 190	$ 278
Office and computer equipment	316	245
Medical devices on rent	806	513
Software	38	38
Furniture and fixtures	27	23
Other assets	102	3
Total	1,479	1,100
Accumulated depreciation	(811)	(629)
Net property and equipment	$ 668	$ 471

Depreciation expense was $182 thousand and $98 thousand for the years ended December 31, 2021 and 2020, respectively.

8. Goodwill and Other Intangible Assets

Changes in the carrying value of goodwill and other intangible assets during the year ended December 31, 2021 consist of the following activity:

	December 31, 2020	Amortization	Impairment	December 31, 2021	Weighted average useful life (in years)
Goodwill	$ 7,260	$ -	$ -	$ 7,260	-
Intangible assets subject to amortization					
Customer relationships - UltraMIST	$ 3,603	$ (546)	$ -	$ 3,057	2.9
Patent	2,263	(121)	-	2,142	6.4
Trade names	679	(37)	-	642	1.9
Other intangible assets	$ 6,545	$ (704)	$ -	$ 5,841	3.8

Future amortization expense is expected to be the following:

Year ending December 31,	Amortization
2022	704
2023	704
2024	704
2025	704
2026	704
Thereafter	2,321
	$ 5,841

Impairment – During the fourth quarter of 2020, the Company determined that the intangible asset for customer relationships related to the biological products was impaired due to significant shortfalls in sales of the products during that period compared with the sales projections used to determine the fair value the intangible asset as of the August 6, 2020 acquisition date. The Company does not expect sales of biological products to sufficiently recover. The estimated fair value of the customer relationships at the acquisition date and at December 31, 2020 were determined using the multi-period excess earnings method. At December 31, 2020, the Company recorded a $7.2 million impairment charge for this intangible asset in the consolidated statements of comprehensive loss.

9. Accrued expenses

Accrued expenses consist of the following at December 31, 2021 and 2020:

	2021	2020
Registration penalties	$ 1,950	$ 264
License fees	893	336
Board of director's fees	507	320
Legal and professional fees	221	196
Other	823	1,011
	$ 4,394	$ 2,127

10. Revenue

Disaggregation of Revenue - The disaggregation of revenue is based on geographical region. The following table presents revenue from contracts with customers for the years ended December 31, 2021 and 2020 (dollars in thousands):

	Year ended December 31, 2021			Year ended December 31, 2020		
	United States	International	Total	United States	International	Total
Accessory and parts revenue	$ 7,770	$ 302	$ 8,072	$ 1,121	$ 88	$ 1,209
Product	2,766	350	3,116	2,179	88	2,267
License fees and other	135	60	195	-	152	152
Topic 606 Revenue	$ 10,671	$ 712	$ 11,383	$ 3,300	$ 328	$ 3,628
Rental income	1,627	-	1,627	429	-	429
Topic 842 Revenue	$ 1,627	$ -	$ 1,627	$ 429	$ -	$ 429
Total Revenue	$ 12,298	$ 712	$ 13,010	$ 3,729	$ 328	$ 4,057

Contract liabilities - As of December 31, 2021 and 2020, the Company has contract liabilities from contracts with customers as follows (dollars in thousands):

	December 31, 2021	December 31, 2020
Service agreements	$ 137	$ 69
Deposit on future equipment purchases	204	-
Total contract liabilities	341	69
Less: current portion	(48)	(32)
Non-current contract liabilities	$ 293	$ 37

During the years ended December 31, 2021 and 2020, the Company recognized revenue related to these contract liabilities of $32 thousand and $61 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 during the year ended December 31, 2021 and 2020 (dollars in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020
Beginning balance	$ 69	$ 128
New service agreement additions	100	2
Deposit on future equipment purchases	204	-
Revenue recognized	(32)	(61)
Total contract liabilities	341	69
Less current portion	(48)	(32)
Non-current contract liabilities	$ 293	$ 37

11. 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 for the ended December 31, 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
Accounts Receivable:		
Customer A	24%	n/a
Customer B	16%	46%

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 for the years ended December 31, 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
Purchases:		
Vendor A	50%	n/a
Vendor B	21%	n/a
Vendor C	n/a	35%
Vendor D	n/a	22%
Vendor E	n/a	11%

12. Accounts Receivable Factoring

Receivable amount transferred at 12/31/2021	2,026
Reserve amount held	(289)
Funds due to factoring at 12/31/2021	1,737

On June 17, 2021, the Company entered into a factoring agreement with Goodman Capital Finance ("Goodman"), 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 are sold with recourse back to the Company, therefore the Company accounts for the arrangement as traditional financing.

13. Notes payable

The following two tables summarize outstanding notes payable as of December 31, 2021 and December 31, 2020 (in thousands):

	Maturity Date	Interest Rate	Conversion Price	Principal	Remaining Debt Discount	Remaining Embedded Conversion Option	Carrying Value
Senior secured promissory note payable, in default	In default	20.25%	n/a	$ 15,000	(3,414)	-	$ 11,586
Convertible promisory notes payable, in default	In default	15.4%	$ 0.1071	6,445	(1,099)	6,255	11,601
Convertible promisory notes payable, related parties, in default	In default	14.0%	$ 0.10	1,596	-	-	1,596
SBA loan #2	February 20, 2026	1.00%	n/a	1,033	-	-	1,033
Advances on future cash receipts	March 11, 2022	n/a	n/a	1,500	(1,054)	-	446
Total debt outstanding, including amounts in default				25,574	(5,567)	6,255	26,262
Less: current maturities, including notes in default				(24,699)	5,567	(6,255)	(25,387)
Total long-term debt as of December 31, 2021				$ 875	$ -	$ -	$ 875

	Maturity Date	Stated Interest Rate	Conversion Price	Principal	Remaining Debt Discount	Carrying Value
Senior secured promissory note payable, in default	In default	20.25%	n/a	$ 15,000	(4,324)	$ 10,676
Convertible promissory notes payable, in default:						
Seller Note	In default	17.00%	$ 0.10	4,000	-	4,000
Convertible promissory notes payable, related parties, in default:						
Convertible promissory notes (HealthTronics), related parties	In default	14.0%	$ 0.10	1,596	-	1,596
SBA loan #1	May 28, 2022	1.00%	n/a	464	-	464
Total debt outstanding, including amounts in default				21,060	(4,324)	16,736
Less: current maturities, including notes in default				(20,917)	4,324	(16,593)
Total long-term debt as of December 31, 2020				$ 143	$ -	$ 143

Senior secured promissory note payable, in default ("Senior Secured Note") - On August 6, 2020, the Company entered into a Note and Warrant Purchase and Security Agreement (the "NWPSA"), with NH Expansion Credit Fund Holdings LP, as noteholder and agent. 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 (the "NH Expansion Warrant") in exchange for cash to support operations, repay outstanding debt and close on the acquisition of the UltraMIST® assets from Celularity, among other transactions. As of December 31, 2020, the Company was in default of the minimum liquidity provisions on the Senior Secured Note. As of December 31, 2021, the Company remains in default of the minimum liquidity provisions on the Senior Secured Note, and, as a result, it is classified in current liabilities in the accompanying consolidated balance sheets. As a result of the default, the Company is accruing interest at the default interest note 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 for the twelve months ended December 31, 2021 was $910 thousand and is included in interest expense. Accrued interest related to the Senior Secured Note was $1.6 million and $642 thousand at December 31, 2021 and December 31, 2020, respectively. Interest expense on the Senior Secured Note was $3.1 million and $1.5 million for the years ended December 31, 2021 and 2020, respectively.

Convertible promissory notes payable, in default ("Seller Note") - On August 6, 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, 2021 and December 31, 2020, the Seller Notes had outstanding accrued interest of $761 thousand and $192 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.

April 2021 Securities Purchase Agreement and Warrants (In default) - On April 20, 2021, the Company entered into a Securities Purchase Agreement (the "Leviston Purchase Agreement"), with Leviston Resources, LLC, an accredited investor ("Leviston") for the sale by the Company in a private placement (the "Private Placement") of (i) the Company's future advance convertible promissory note in an aggregate principal amount of up to $3.4 million (the "Leviston Note") and (ii) a warrant to purchase an additional 16,666,667 shares of common stock of the Company (the "Leviston Warrant"). The Leviston Warrant has an exercise price of $0.18 per share and a four-year term. The closing of the Private Placement occurred on April 20, 2021 (the "Leviston Closing Date").

As noted above, on April 20, 2021, the Company issued the Leviston Note to the Purchaser in an aggregate principal amount of up to $3.4 million (the "Aggregate Amount"), which shall be advanced in disbursements by the Purchaser ("Leviston Disbursements"), as set forth in the Leviston Note. On May 14, 2021, the Leviston Note was amended to increase the Aggregate Amount to $4.2 million. On April 21, 2021, the Purchaser advanced a Leviston Disbursement of $750 thousand, which is net of an original issue discount of 8%. On May 14, 2021, the Purchaser advanced a second Leviston Disbursement of $750 thousand, also net of an original issue discount of 8%. A $250 thousand Leviston Disbursement was made on September 3, 2021, which was subject to the same terms and conditions of the April and May Leviston Disbursements. In addition, a $500 thousand disbursement was made on September 3, 2021 in accordance with notes issued to five institutional investors (the "Five Institutions' Notes"), which were subject to substantially the same terms and conditions as the Leviston Disbursements. Accrued interest related to the Securities Purchase Agreement and Warrants was $169 thousand at December 31, 2021. Interest expense on the Securities Purchase Agreement and Warrants was $169 thousand for the year ended December 31, 2021.

December 2021 Advance on Future Receipts Financing - On December 22, 2021, the Company paid off the remaining balance of $650 thousand from the September 27, 2021 advance and received $758 thousand in cash proceeds related to its entry into a non-recourse agreement for the sale of $1.5 million of future receipts to GCF. In conjunction with the 24-week agreement, the Company is obligated to remit to GCF a minimum of $59 thousand of receipts each week for the first six weeks and receipts of $98 thousand for the remaining 18 weeks. After considering the payments made at closing, the Company will record an initial liability of $1.5 million and a debt discount of approximately $90 thousand, which represents the original issue discount and the fees paid in conjunction with the financing. The debt discount will be amortized to interest expense over the life of the agreement. The Company will begin making the required minimum weekly payments January 3, 2022 and is obligated to continue through June 13, 2022. At closing, the Company also issued warrants to purchase 8,333,334 shares of the Company's common stock to affiliates of GCF. The warrants have an exercise price of $0.18 per share and expire four years after issuance. The Company has evaluated the terms of the warrants and after review has determined that these warrants meet the definition of a derivative liability and accordingly, were recorded as additional discount against the debt at issuance.

Warrant issuances to Leviston and Five Institutions' in April, May and September 2021

On April 20, 2021, May 14, 2021 and September 3, 2021, respectively, Leviston was issued 3,968,254, 3,968,254 and 1,322,751, warrants for shares of common stock. On September 3, 2021, the Company also issued a total of 2,777,779 warrants for shares of common stock to Five Institutions. After evaluating the terms of the warrants the Company determined that these warrants meet the definition of a derivative liability and accordingly, were recorded as additional discount against the debt at issuance. See details of the associated warrant issuances at Note 15 – Warrant Liabilities.

Embedded Conversion Option Liability

The disbursements made in April, May and September 2021 under the Leviston Notes and the Five Institutions' Notes included a Conversion Option that meets the definition of a derivative liability and, accordingly, is required to be bifurcated. The fair value of Conversion Option liability was determined by using a binomial pricing model (dollars in thousands):

Valuation at December 31, 2021	Principal	Conversion Price[(1)]	Interest Rate (annual) [(2)]	Volatility (annual) [(3)]	Time to Maturity (Years)	Fair Value of Conversion Option
Leviston Issuances	$ 1,902	0.109	0.16%	303.20%	0.4	$ 5,204
Five Institution Issuances	544	0.109	0.26%	249.00%	0.7	1,051
	$ 2,446					$ 6,255

(1) Based on the terms provided in the warrant agreement to purchase common stock of the Company as of December 31, 2021.
(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.

Valuation at issue dates	Principal	Conversion Price[1]	Interest Rate (annual) [2]	Volatility (annual) [3]	Time to Maturity (Years)	Fair Value of Conversion Option
Leviston Issuances	$ 1,902	0.18	0.07%	73.10%	1.0	$ 3,206
Five Institution Issuances	544	0.18	0.08%	80.10%	1.0	932
	$ 2,446					$ 4,138

(1) Based on the terms provided in the warrant agreement to purchase common stock of the Company on the stated issuance dates.
(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.

Interest rates on Leviston and Five Institutions' Notes, Conversion Option, and Loss on Issuance

The Leviston Disbursements and Five Institutions' Disbursements in April, May and September 2021, bear interest at the rate of 5% per annum and the default rate of 15%. The Leviston Note and Five Institutions' Notes contains a conversion option ("Conversion Option") and because they are in default, the Leviston and Five Institutions' Notes are convertible into common shares of the Company at a conversion price of 75% of the lowest VWAP during the ten trading days ending on the conversion date. For the Five Institutions' Note this conversion rate shall be no lower than $0.01. The Conversion Option within the Leviston and Five Institutions' Notes are required to be bifurcated at fair value, which was approximately $1.4 million on the April disbursement and $1.4 million on the May disbursement and $1.4 million on the September disbursements, which resulted in additional debt discounts being recorded at each disbursement date. Because the combined fair value of the applicable warrants and conversion option exceeded the face value of the note, the additional amount beyond the face value is recorded as a loss on issuance of $1.4 million on the April disbursement and $1.1 million on the May disbursement and $1.1 million on the September disbursement. The remaining disbursements up to the Aggregate Amount are subject to the satisfaction of certain terms and conditions set forth in the applicable notes. The disbursements bear an interest at a rate of five percent (5%) per annum and have a maturity date of twelve (12) months from the date of issuance. The Leviston and Five Institutions' Notes are convertible at the option of the holder into shares of the common stock of the Company at a conversion price per share equal to the lesser of (i) $0.18, and (ii) ninety percent (90%) of the closing price for a share of common stock reported on the OTCQB on the effective date of the Registration Statement (as defined below).

The Leviston and Five Institutions' Note contains customary events of default and covenants, including limitations on incurrences of indebtedness and liens.

Pursuant to the Leviston Purchase Agreement and purchase agreements with the Five Institutions (the "Five Institutions' Purchase Agreements"), the Company has agreed, within a reasonable period of time following the applicable closing date, and in any event prior to any Leviston Disbursement under the Leviston Note subsequent to the initial Leviston Disbursement, to enter into a security agreement in favor of the Leviston or the Five Institutions, as applicable, securing the Company's obligations under the applicable notes.

The rights of Leviston and the Five Institutions to receive payments under the applicable notes are subordinate to the rights of North Haven Expansion pursuant to the subordination agreements that the Company and Leviston, and the Company and the Five Institutions entered into with North Haven Expansion on April 20, 2021 and September 3, 2021, respectively, in connection with the Private Placement (the "Subordination Agreement").

In connection with the Leviston Purchase Agreement, the Company entered into a registration rights agreement with the Leviston on April 20, 2021 (the "Leviston Registration Rights Agreement") pursuant to which the Company agreed to file a registration statement (the "Registration Statement") with the SEC no later than thirty days following the Leviston Closing Date for the registration of 100% of the maximum number of the shares issuable upon conversion of the Leviston Note and exercise of the Leviston Warrants issued pursuant to the Leviston Purchase Agreement (the "Leviston Registrable Securities"). The Company shall use its best efforts to keep the Registration Statement continuously effective under the Securities Act of 1933, as amended (the "Securities Act"), until all Leviston Registrable Securities have been sold, or may be sold without the requirement to be in compliance with Rule 144(c)(1) of the Securities Act and otherwise without restriction or limitation pursuant to Rule 144 of the Securities Act, as determined by the counsel to the Company. The Company has yet to file the Registration Statement and, under the terms of the Leviston Registration Rights Agreement, it is obligated to pay in cash a one-time aggregate amount of $250 thousand to the holders of the Leviston Notes, plus 1% of the outstanding principal for each 30-day period during which the Company continues not to have in-place an effective Registration Statement.

On August 31, 2021, Leviston notified the Company that it was in default of the Leviston Purchase Agreement effective June 11, 2021, for failure to timely file a Registration Statement. From the date of the default, interest on the amounts due to Leviston is calculated at the default interest rate of 15% in addition to the registration penalties stated above.

The Company also entered into registration rights agreements with each of the Five Institutions on September 3, 2021. The terms and conditions of the Five Institutions' registration rights agreements are substantially similar to the Leviston Registration Rights Agreement, with two exceptions: (1) the Five Institutions may be entitled to a pro-rata share of the $250 thousand one-time aggregate amount (approximately $56 thousand) and (2) the 1% of outstanding principal payment amount for each 30-day period is capped at 5% of outstanding principal.

Convertible promissory notes payable (HealthTronics), in default - On August 6, 2020, the Company issued to HealthTronics, Inc. a convertible note payable in the amount of $1.4 million (the "HealthTronics Note"). The HealthTronics 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 HealthTronics Note and, accordingly, it began accruing additional interest of 2.0% in addition to the 12.0% stated interest rate, as of the date of the default. The convertible promissory note is expressly subordinate to the Senior Secured Notes. The Company may prepay the outstanding principal balance, together with any accrued but unpaid interest without premium or penalty. On December 31, 2021 and December 31, 2020, accrued interest of $241 thousand and $66 thousand, respectively, remained outstanding on the HealthTronics Note.

As the Seller Note was not repaid prior to January 1, 2021, HealthTronics may elect to convert the outstanding principal amount plus any accrued but unpaid interest thereon into shares of the Company's common stock, at a conversion price of $0.10 per share. 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 (Stolarski), in default - On August 6, 2020, the Company issued to A. Michael Stolarski, a member of the board of directors and an existing shareholder, a convertible promissory note in the principal amount of $223 thousand (the "Stolarski Note"). The Stolarski 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 Stolarski Note and, accordingly, it began accruing additional interest of 2.0% in addition to the 12.0% initial rate, as of the date of the default. On December 31, 2021 and December 31, 2020 accrued interest of $41 thousand and $11 thousand, respectively, remained outstanding on the Stolarski Note. The Stolarski Note is expressly subordinate to the Senior Secured Notes. The Company may prepay the outstanding principal balance, together with any accrued but unpaid interest without premium or penalty.

As the Stolarski Note was not repaid prior to January 1, 2021, the holder may elect to convert the outstanding principal amount plus any accrued but unpaid interest thereon into shares of common stock at a conversion price of $0.10 per share. 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.

September 2021 Advances on Future Receipts Financing – On September 27, 2021, the Company received $703 thousand in cash proceeds related to its entry into a non-recourse agreement for the sale of $1.0 million of future receipts to GCF Resources LLC ("GCF"). In conjunction with the 24-week agreement, the Company is obligated to remit to GCF a minimum of $59 thousand of receipts each week, with the sum of the first four payments occurring at closing, which was September 27, 2021. After taking into account the payments made at closing, the Company recorded an initial liability of $763 thousand and a debt discount of approximately $60 thousand, which represents the original issue discount and the fees paid in conjunction with the financing. The debt discount will be amortized to interest expense over the life of the agreement. The Company began making the required minimum weekly payments October 25, 2021. At closing, the Company also issued warrants to purchase 5,555,556 shares of the Company's common stock to affiliates of GCF. The warrants have an exercise price of $0.18 per share and expire four years after issuance. The Company determined that these warrants meet the definition of a derivative liability and accordingly, were recorded as additional discount against the debt at issuance.

SBA Loan #1 - The Company received a letter from the Small Business Administration ("SBA") dated August 27, 2021 forgiving approximately $454 thousand of the SBA Loan #1 principal and $6 thousand of interest, which resulted in the Company recognizing a gain on extinguishment of debt of $460 thousand during the third quarter of 2021.

SBA Loan #2 – On February 20, 2021, the Company received proceeds from a second SBA loan ("SBA Loan #2") in the amount of $1.03 million from Northeast Bank, as lender, pursuant to the Paycheck Protection Program ("PPP") under the CARES Act. SBA Loan #2 is evidenced by a promissory note that matures on February 20, 2026 and bears interest of 1% per annum. Equal monthly payments of principal and interest commence in June 2022, after both a 24-week "covered period" and a 10-month "deferment period," as defined in the promissory note and current SBA regulations. The SBA Loan #2 contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties and covenants. The SBA Loan #2 may be prepaid by the Company at any time prior to maturity with no penalties.

All or a portion of SBA Loan #2 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 ultimate forgiveness of SBA Loan #2 is also contingent upon regulatory authorities concurring with management's good faith assessment that the current economic uncertainty made the loan request necessary to support ongoing operations. If, despite the Company's good-faith belief that given the circumstances the Company satisfied all eligibility requirements for SBA Loan #2, the Company is later determined to have violated any applicable laws or regulations or it is otherwise determined that the Company was ineligible to receive SBA Loan #2, the Company may be required to repay SBA Loan #2 in its entirety and/or be subject to additional penalties. In the event SBA Loan #2, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal. As of December 31, 2021, $158 thousand is included in current liabilities and the remainder of the $875 thousand loan balance is included in non-current liabilities in the accompanying consolidated balance sheets.

14. Common Stock Purchase Warrants

A summary of the warrant activity during the years December 31, 2021 and 2020 is as follows:

	Warrants	Weighted Average Exercise Price per share	Weighted Average Remaining Contractual Life (years)
Warrants at December 31, 2019	9,474,091	$ 0.11	5.03
Issuances	189,182,645	0.19	
Exercised	(8,200,000)	0.10	
Forfeited or expired	(100,000)	0.20	
Outstanding at December 31, 2020	190,356,736	$ 0.19	3.43
Issuances	25,925,928	0.18	
Exercised	(11,400,000)	0.01	
Forfeited or expired	-	-	
Outstanding at December 31, 2021	204,882,664	$ 0.20	2.54

On February 3, 2021, the Company issued 10,925,000 shares of its commons stock to LGH upon the cashless exercise of 11,400,000 of the LGH Warrants under the terms of the warrant agreement. After this cashless exercise, 23,600,000 of LGH Warrants remain outstanding.

15. Fair Value Measurements

In accordance with ASC 820 (Fair Value Measurements and Disclosures), the Company uses various inputs to measure the outstanding warrants and certain embedded conversion features associated with a convertible debt on a recurring basis to determine the fair value of the liability.

The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy as of December 31, 2021 and 2020 (in thousands):

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

	Fair value measured at December 31, 2020			
	Fair value at December 31, 2020	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 8,855	-	-	8,855
Embedded conversion option	-	-	-	-
Total fair value	8,855	-	-	8,855

There were no transfers between Level 1, 2 or three during the years ended December 31, 2021 and 2020.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2021 and 2020. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g. changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs (in thousands):

	Warrant Liability	Embedded Conversion Feature	Total
Balance December 31, 2019	$ -	$ -	$ -
Warrants classified as liabilities	11,955	-	11,955
Warrants reclassified as equity	(6,293)	-	(6,293)
Change in fair value	3,193	-	3,193
Balance December 31, 2020	$ 8,855	$ -	$ 8,855
Cashless exercise	(2,030)	-	(2,030)
Warrants classified as liabilities	2,282	-	2,282
Transfer to convertible feature	-	4,139	4,139
Change in fair value	507	2,116	2,623
Balance December, 2021	$ 9,614	$ 6,255	$ 15,869

A summary of the warrant liability activity for the year ended December 31, 2021 is as follows:

	Warrants Outstanding	Fair Value per Share	Fair Value
Balance December 31, 2019	-	$ -	$ -
Warrants classified as liabilities	112,210,902	0.11	11,955,454
Warrants reclassified as Equity	(64,119,742)	0.10	(6,292,695)
Gain on remeasurement of warrant liability	-		3,192,620
Balance December 31, 2020	48,091,160	$ 0.18	$ 8,855,379
Cashless exercise of LGH Warrants	(11,400,000)	0.18	(2,030,052)
Warrants classified as liabilities	25,926,028	0.10	2,282,262
Gain on remeasurement of warrant liability	-		506,545
Balance December, 2021	62,617,188	$ 0.15	$ 9,614,134

Significant Black Scholes valuation model inputs related to the Company's different Warrants at December 31, 2021 and 2020 are listed below.

	2021	2020
Weighted average expected life in years	4.67	7.00
Weighted average volatility	116%	121%
Weighted average risk free interest rate	1.2%	0.5%
Expected dividend yield	0.00%	0.00%

16. Leases

The following is a summary of the Company's right of use assets and lease liabilities at December, 2021 and 2020 (in thousands):

	December 31, 2021			December 31, 2020		
	Operating Leases	Financing Leases	Total	Operating Leases	Financing Leases	Total
Right of use assets	$ 725	$ 626	$ 1,351	$ 725	$ 644	$ 1,369
Less: Accumulated amortization	(574)	(433)	(1,007)	(339)	(235)	(574)
Right of use assets, net	$ 151	$ 193	$ 344	$ 386	$ 409	$ 795
Lease liabilities	$ 157	$ 229	$ 386	$ 415	$ 427	$ 842
Less: current portion	(83)	(185)	(268)	(257)	(194)	(451)
Lease Liabilities	$ 74	$ 44	$ 118	$ 158	$ 233	$ 391

Total lease costs for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	2021	2020
Finance lease costs:		
Amortization of right-of-use assets	$ 217	$ 94
Interest on lease liabilities	41	33
Operating lease costs	350	118
Total lease costs	$ 608	$ 245

The following summarizes cash paid for amounts included in the measurement of lease liabilities as well as the related right-of-use assets obtained for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from finance leases	$ (234)	$ (103)
Operating cash flows from operating leases	$ (350)	$ (118)

Operating Leases - As of December 31, 2021, the maturities of the Company's operating lease liability, which have initial or remaining lease terms in excess of one year, consist of the following (in thousands):

	Amount
Year ending December 31,	
2022	$ 96
2023	68
2024	11
Total lease payments	175
Less: Present value adjustment	(18)
Lease liability	$ 157

As of December 31, 2021, the Company's operating leases had a weighted average remaining lease term of 1.1 years and a weighted average discount rate of 12.0%.

Rent expense for the years ended December 31, 2021 and 2020 was $362 thousand and $297 thousand, respectively.

Financing Lease - As of December 31, 2021, the maturities of the Company's financing lease liability, which have initial or remaining lease terms in excess of one year, consist of the following (in thousands):

	Amount
Year ending December 31,	
2022	$ 200
2023	18
Total lease payments	218
Present value adjustment	11
Lease liability	$ 229

As of December 31, 2021, the Company's financing leases had a weighted average remaining lease term of 1.0 years based on annualized base payments expiring through 2023 and a weighted average discount rate of 13.2%.

As of December 31, 2021, the Company did not have additional operating or financing leases that have yet commenced.

17. Common Stock

On July 23, 2020, in connection with the Company's 2020 Annual Meeting of Stockholders, the Company's stockholders approved, among other matters, an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 355,000,000 to 600,000,000.

Also on July 23, 2020, the Company's stockholders approved the Company to amend the Company's Articles of Incorporation to effect a reverse split of the Company's outstanding common stock at a ratio of between 1-for-10 and 1-for-50, with the exact ratio to be determined by the board of directors of the Company in its sole discretion. The Company has not yet effected a reverse split of its stock.

On December 30, 2020, the Company held a special meeting of stockholders (the "Special Meeting"). At the Special Meeting, the Company's stockholders approved an amendment to the Company's Articles of Incorporation, as amended, to increase the number of authorized shares of its common stock, par value $0.001 per share, to 800,000,000, and the Company filed a Certificate of Amendment to its Articles of Incorporation, as amended with the Secretary of State of the State of Nevada on December 30, 2020 to reflect this amendment, which became effective on December 30, 2020.

18. Preferred Stock

On January 31, 2020, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series C Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 90 shares of our preferred stock as Series C Convertible Preferred Stock.

On February 6, 2020, the Company entered into a Series C Preferred Stock Purchase Agreement (the "Series C Purchase Agreement") with certain accredited investors for the sale by the Company in a private placement of an aggregate of 90 shares of the Company's Series C Convertible Preferred Stock, par value $0.001 per share at a stated value equal to $25 thousand per share, for an aggregate total purchase price of $2.3 million.

On May 14, 2020, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series D Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate eight shares of our preferred stock as Series D Convertible Preferred Stock.

On May 14, 2020, the Company entered into a Series D Preferred Stock Purchase Agreement (the "Series D Purchase Agreement") with certain accredited investors for the sale by the Company in a private placement of an aggregate of eight shares of the Company's Series D Convertible Preferred Stock, par value $0.001 per share at a stated value equal to $25 thousand per share (the "Series D Preferred Stock"), for an aggregate total purchase price of $200 thousand.

Subject to the terms of the Certificates of Designation, each share of Series C Preferred Stock and Series D Preferred Stock is convertible into shares of common stock of the Company at a rate equal to the stated value of such share of Series C Preferred Stock and Series D Preferred Stock of $25 thousand, divided by the conversion price of $0.14 per share (subject to adjustment from time to time upon the occurrence of certain events as described in the Certificate of Designation). The Certificates of Designation became effective upon filing with the Secretary of State of the State of Nevada. If all outstanding shares of Series C Preferred Stock and Series D Preferred Stock were converted into common stock at the original conversion rate, such shares would convert into an aggregate of 17,500,000 shares of common stock.

On September 20, 2020, the Series C and D holders converted their preferred shares into 17,499,958 shares of common stock.

19. Commitments and Contingencies

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

Supplier disputes - In May 2021, the Company received notification alleging that it is not in compliance with the license agreement with Celularity entered into in connection with the acquisition of the UltraMIST® assets. The Company has 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.

20. Related party transactions

February 2018 dermaPACE® Purchase - On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation ("PSWC"), and Premier Shockwave, Inc., a Georgia Corporation ("PS"). Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company's board of directors and a shareholder of the Company. The agreement provides for the purchase by PSWC and PS of dermaPACE® System and related equipment sold by the Company along with limited but exclusive distribution rights to provide dermaPACE® Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. The agreement also 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. The purchase price for this agreement is 5.5 times the annualized EBITDA for the six months trailing the change of control plus the book value of the equipment and working capital.

During the years ended December 31, 2021 and 2020, respectively, the Company recorded $32 thousand and $45 thousand in revenue from this entity. In addition, contract liabilities include a balance of $38 thousand at December 31, 2021 and $70 thousand at December 31, 2020 from this related party.

March 2021 Future Purchase of Equipment - In March 2021, PSWC paid the Company $125 thousand as a deposit for future purchase of new medical equipment.

July 2021 dermaPACE® Purchase - On July 1, 2021, the Company purchased unused DermaPace 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.

July 2021 Rental Equipment Agreement - Also, effective July 1, 2021, the Company entered into a short-term equipment rental agreement with PSWC, whereby the Company obtained DermaPace equipment from PSWC for $3,600 per month.

October 2021 Advance from Director – On October 27, 2021 the Company received $25 thousand from A. Michael Stolarski (the "Stolarski Advance"). In exchange for the Stolarski Advance, as well as the $125 thousand deposit received in March 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.

April 2022 Advance from Director - On April 1, 2022 the Company entered into an Advance 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 ("Stolarski Advance").

The Stolarski Advance has 18 UltraMIST® systems used as collateral (the "Collateral") and the Company has agreed to repurchase the Collateral at $256 thousand.

21. 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 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 particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are 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, 2021 and 2020, the Stock Incentive Plan reserved a total of 35,000,000 and 35,000,000, respectively, shares of common stock for grant.

The following is a summary of the activity of the Stock Incentive Plan for the years ended December 31, 2021 and 2020:

	Options	Weighted Average Exercise Price per share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	34,303,385	$ 0.28	6.62	$ 981,088
Granted	100,000	0.26		
Exercised	(325,000)	0.15		
Forfeited or expired	(2,140,000)	0.71		
Outstanding at December 31, 2020	31,938,385	0.26	5.94	$ 1,372,116
Granted	-	-		
Exercised	-	-		
Forfeited or expired	(179,000)	0.18		
Outstanding at December 31, 2021	31,759,385	0.26	4.92	$ 1,056,236
Vested and exercisable at December 31, 2021	31,409,385	$ 0.26	4.92	$ 1,056,236

On December 31, 2021, there were 3,240,615 shares of common stock available for grant under the Stock Incentive Plan.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the year ended December 31, 2020 is shown below:

	2020
Weighted average expected life in years	5.00
Weighted average volatility	124%
Weighted average risk free interest rate	1.6%
Expected dividend yield	0.00%

For the years ended December 31, 2021 and 2020, the Company recognized $0 thousand and $22 thousand, respectively, as compensation cost related to options granted. The compensation cost is included in operating expenses in the accompanying consolidated statements of comprehensive loss. As of December 31, 2021 and 2020, there are no unamortized compensation costs related to options granted.

22. Joint ventures

On December 13, 2019, the Company entered into a joint venture agreement (the "Agreement") with Universus Global Advisors LLC, a limited liability company organized under the laws of the State of Delaware ("Universus"), Versani Health Consulting Consultoria em Gestão de Negócios EIRELI, an empresa individual de responsabilidade limitada organized under the laws of Brazil ("Versani"), Curacus Limited, a private limited company organized under the laws of England and Wales ("Curacus"), and certain individual citizens of Brazil and the Czech Republic (the individuals together with Curacus, the "IDIC Group"). The principal purpose of the joint venture company will be to manufacture, import, use, sell, and distribute, on an exclusive basis in Brazil, dermaPACE devices and wound kits consisting of a standard ultrasound gel and custom size sterile sleeves used for the treatment of various acute and chronic wounds using extracorporeal shockwave therapy technology. The joint venture company will also provide treatments related to the dermaPACE devices. The IDIC Group has agreed to pay to the Company a partnership fee in the total amount of $600,000 for the granting of exclusive territorial rights to the joint venture company to distribute the dermaPACE devices and wound kits in Brazil. The $600,000 partnership fee was received and recognized as nonoperating income during the year ended December 31, 2020. The IDIC Group will also have the right to receive prioritized dividends until full reimbursement of the partnership fee and expenses incurred in the formation of the joint venture company, which are required to be paid by the IDIC Group.

23. 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 for the years ended December 31, 2021 and 2020 are as follows (dollars in thousands):

	2021	2020
Domestic	$ (27,208)	$ (30,945)
Foreign	(23)	8
Net loss before income taxes	$ (27,231)	$ (30,937)

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 of a deferred tax asset will not be realized.

On March 27, 2020, the CARES Act was enacted in response to COVID-19 pandemic. Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. The CARES Act made various tax law changes including among other things (i) increasing the limitation under Section 163(j) of the Internal Revenue Code of 1986, as amended (the "IRC") for 2019 and 2020 to permit additional expensing of interest (ii) enacting a technical correction so that qualified improvement property can be immediately expensed under IRC Section 168(k), (iii) making modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes and (iv) enhancing the recoverability of alternative minimum tax credits. The CARES Act did not have a material impact on the Company.

The income tax provision (benefit) from continuing operations consists of the following at December 31, 2021 and 2020 (dollars in thousands):

Current:	2021	2020
Federal	$ -	$ -
State	28	-
Foreign	-	-
	28	-
Deferred:		
Federal	(5,038)	(5,420)
State	(869)	(964)
Foreign	4	1
Change in valuation allowance	5,903	6,383
	$ 28	$ -

At December 31, 2021 and 2020, 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, 2021 and 2020 to pretax loss from operations as a result of the following for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Tax expense (benefit) at statutory rate	$ (5,718)	$ (6,498)
Increase (reduction) in income taxes resulting from:		
State income taxes (benefits), net of federal benefit	(837)	(913)
Non-deductible gain on warrant adjustment valuation	417	670
Income from foreign subsidiaries	-	2
Change in valuation allowance	5,903	6,383
Registration penalties	354	-
Other	(91)	356
Income tax expense (benefit)	$ 28	$ -

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2021 and 2020 are as follows (dollars in thousands):

	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 33,238	$ 28,048
Net operating loss carryforwards - foreign	23	19
Excess of tax basis over book value of property and equipment	14	8
Excess of tax basis over book value of intangible assets	1,632	1,811
Stock-based compensation	1,613	1,613
Accrued employee compensation	698	427
Capitalized equity costs	49	49
Net change in reserve accounts	898	287
	38,165	32,262
Valuation allowance	(38,165)	(32,262)
Net deferred tax asset	$ -	$ -

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, 2021 and 2020.

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 and state net operating loss carryforwards of approximately $77.9 million from years ending December 31, 2005 through December 31, 2017 will begin to expire in 2025. The federal and state net operating loss carryforward for the years ended December 31, 2018 through 2021 of approximately $56.5 million will not expire. The foreign net operating loss carryforward at December 31, 2019 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 in the course of 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, 2021 and 2020. 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, 2021 and 2020, the Company did not have any amounts recorded for interest and penalties.

24. Subsequent events

Warrant Exercises – The Company received $0.1 million in proceeds related to the exercise of 15.9 million warrants (cash and cashless) and issued 14.9 million shares.

Second Amendment to Note and Warrant Purchase and Security Agreement - The Company received $3.0 million in proceeds related to the issuance of a $3.0 million dollar note, 20.7 million Advisor shares, and 15.5 million warrants with an exercise price of $0.18 and a 10 year term.

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, 2021. 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, 2021.

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, 2021. 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).

We previously reported three material weaknesses in our internal control over financial reporting process resulting from a lack of internal expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distribution agreements, a lack of internal resources to analyze and properly apply generally accepted accounting principles to accounting for equity components of service agreements with select vendors and cybersecurity breaches from email spoofing in 2019. The company has remedied the cybersecurity breaches and email spoofing in 2020.

As of 2021 the company still has identified the following material weaknesses

1. Expertise and resources to analyze and properly apply generally accepted accounting principles to complex and non-routine transactions such as complex financial instruments and derivatives and complex sales distribution agreements.

2. A lack of internal resources to analyze and properly apply generally accepted accounting principles to accounting for financial instruments included in service agreements with select vendors.

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

As a result, management concluded that its internal control over reporting was not effective as of December 31, 2021.

Remediation Plan

During 2021, we engaged external consultants with appropriate experience applying GAAP technical accounting guidance, and we have hired additional accounting personnel both internal and external. We engaged external consultants to review revenue recognition for new products, lease agreements, internal controls and related procedures and review of documentation of internal controls in addition to new equity and debt financing arrangements. Accounting memos were produced for all technical issues during 2020 and reviewed with management. The Company will continue to implement and review new controls to address these issues.

We have also implemented cybersecurity training for all employees and redesign of procedures that cyber security breaches may impact and worked with our third-party IT vendor to develop a training plan for all existing and new employees related to cyber and implemented related controls around information technology infrastructure. In addition, an additional employee was hired to assist with the management of IT controls and enhance internal IT resources. Going forward, this employee will monitor our third-party IT vendor's testing and monitoring efforts and where necessary implement new controls as the Company grows. These internal controls have been documented and procedures implemented.

There is no assurance that the measures described above will be sufficient to remediate the previously identified material weaknesses.

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, 2021 that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting, except as disclosed in "Remediation of Material Weaknesses" 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	53	Director, Chairman and Chief Executive Officer
Lisa E. Sundstrom	52	Chief Financial Officer and Chief Talent Officer
Peter Stegagno	62	Chief Operating Officer
Iulian Cioanta, PhD	59	Chief Science and Technology Officer
John Schlechtweg	42	Chief Revenue Officer
A. Michael Stolarski	51	Director
Jeff Blizard	53	Director
Ian Miller	46	Director
Jim 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.

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. In December 2015, Ms. Sundstrom was promoted to Chief Financial Officer. Ms. Sundstrom has extensive financial accounting experience with Automatic Data Processing (ADP) and Mitsubishi Consumer Electronics. During 2021 she also assumed the role of Chief Talent Officer. 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 sixteen years of 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.

John Schlechtweg joined the Company as Chief Revenue Officer in August 2020. Mr. Schlechtweg brings to the Company over fifteen years of experience in the biotech, pharmaceutical and medical device sales and marketing. He most recently served as Senior Director of Sales for Celularity, and other medical companies including Alliqua, Shire Regenerative Medicine, Accelecare, Organogenesis, Inc., and Merck Scherng-Plough. Mr. Schlechtweg graduated from Southern Connecticut State University with a Masters of Business Administration and from Utica College of Syracuse University with a Bachelor of Arts.

Jeff 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 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 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 operation 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.

John F. Nemelka joined the Company as a member of the board of directors in October of 2009 and joined SANUWAVE, Inc. as a member of the board of directors in August of 2005. Mr. Nemelka founded NightWatch Capital Group, LLC, an investment management business, and served as its Managing Principal since its incorporation in July 2001 until its liquidation in December 2015. From 1997 to 2000, he was a Principal at Graham Partners, a private investment firm and affiliate of the privately-held Graham Group. From 2000 to 2001, Mr. Nemelka was a Consultant to the Graham Group. Mr. Nemelka brings to our board of directors a diverse background with both financial and operations experience. He holds a B.S. degree in Business Administration from Brigham Young University and an M.B.A. degree from the Wharton School at the University of Pennsylvania. Mr. Nemelka resigned from the Company's board of directors effective April 10, 2022.

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 Company adopted a formal Corporate Governance policy in January 2012 which included establishing formal board committees and a code of conduct for the board of directors and the Company.

The Board of Directors

Recent Developments

The Company's current board of directors consists of five members, four of whom have been determined by the board to be "independent" as defined under the rules of the OTC stock market.

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, taking into account 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 has determined that it is currently in the best interest of the Company and its shareholders to combine the roles of chairman of the board and chief executive officer.

The Company believes, however, that there is no single leadership structure that is the best and most effective in all circumstances and at all times. 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. The Company's current board of directors consists of five members, four of whom has 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 and Rule 10A-3 under the Exchange Act. Beginning in July 2021, the Company's board of directors determined that all of its current members would also be members of each of the audit, compensation and corporate governance committees.

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 current members of the Company's audit committee are A. Michael Stolarski (Acting Chairperson), Ian Miller 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. Stolarski, 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.

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. Among other things, the audit committee is responsible for overseeing the Company's accounting and financial reporting processes and audits of the Company's financial statements, reviewing and discussing with the independent auditors the critical accounting policies and practices for the Company, engaging in discussions with management and the independent auditors to assess risk for the Company and management thereof, and 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.

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 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 nominating and governance committee are Ian Miller 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.

The nominating and corporate governance committee's charter outlines how the nominating and corporate governance committee fulfills its responsibilities for assessing the qualifications and effectiveness of the current board members, assessing the needs for future board members, identifying individuals qualified to become members of the board and its committees, and recommending candidates for the board of director's selection as director nominees for election at the next annual or other properly convened meeting of shareholders.

The nominating and corporate governance committee considers director candidates recommended by shareholders for nomination for election to the board of directors. The committee applies the same standards in considering director candidates recommended by the shareholders as it applies to other candidates. Any shareholder entitled to vote for the election of directors may recommend a person or persons for consideration by the committee for nomination for election to the board of directors. The Company must receive written notice of such shareholder's recommended nominees(s) no later than January 31st of the year in which the shareholder wishes such recommendation to be considered by the committee in connection with the next meeting of shareholders at which the election of directors will be held. To submit a recommendation, a shareholder must give timely notice thereof in writing to the Secretary of the Company. A shareholder's notice to the Secretary shall set forth: (i) the name and record address of the shareholder making such recommendation and any other shareholders known by such shareholder to be supporting such recommendation; (ii) the class and number of shares of the Company which are beneficially owned by the shareholder and by any other shareholders known by such shareholder to be supporting such recommendation; (iii) the name, age and five year employment history of such recommended nominee; (iv) the reasons why the shareholder believes the recommended nominee meets the qualifications to serve as a director of the Company; and (v) any material or financial interest of the shareholder and, if known, the recommended nominee in the Company.

Shareholder Communications with the Board of Directors

The board of directors has implemented a process for shareholders to send communications to the board of directors. Shareholders who wish to communicate directly with the board of directors or any particular director should deliver any such communications in writing to the Secretary of the Company. The Secretary will compile any communications they receive from shareholders 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 shareholder.

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 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. Officers, directors and greater than 10% shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Except as set forth herein, based solely upon a review of the Forms 3, 4 and 5 (and amendments thereto) furnished to us for our fiscal year ended December 31, 2021, we have determined that our directors, officers and greater than 10% beneficial owners complied with all applicable Section 16 filing requirements.

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table for Fiscal Years 2021 and 2020

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, 2021 and 2020.

Name and Principal Position	Year	Salary ($)	Option Awards ($) (2)	All Other Compensation ($)(3)	Total ($
Kevin A. Richardson, II	2021	$350,000	-	$ 49,310	$399,3
Chairman of the Board and Chief Executive Officer (principal executive officer)	2020	$335,417(1)	-	$ 37,180	$372,5
Shri P. Parikh (4)	2021	$ -	-	$ -	$
President, Healthcare	2020	$305,301	-	$ 23,699	$329,0
Peter Stegagno	2021	$200,000	-	$ 47,833	$247,8
Chief Operating Officer	2020	$188,333	-	$ 28,905	$217,2
Lisa E. Sundstrom	2021	$200,000	-	$ 52,023	$251,0
Chief Financial Officer (principal financial officer)	2020	$191,667	-	$ 23,347	$215,0

(1) Amounts reflect (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 2020 (which aggregate amount is also reflected in the Director Compensation Table, below).

(2) Amounts shown in this column do not reflect the dollar amounts actually received by our NEOs. Instead, these amounts reflect the aggregate grant date fair value of each stock or option award in the respective fiscal year, computed in accordance with the provisions of FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 18 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

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

(4) Mr. Parikh was named President, Healthcare of the Company effective May 31, 2018. On May 14, 2020, Mr. Parikh notified the Company of his decision to resign effective June 30, 2020.

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 nonstatutory 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 particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are nonstatutory 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 which is approved by the board of directors of the Company. The Stock Incentive Plan had 35,000,000 shares of common stock reserved for grant at December 31, 2020 and 2019, respectively.

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 individual's 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.

On December 31, 2021, there were 2,568,281 shares of common stock available for grant under the Stock Incentive Plan. For the years ended December 31, 2021 and 2020, there were 0 and 0 options, respectively, granted to the Company's executive officers under the Stock Incentive Plan.

Outstanding Equity Awards at 2021 Fiscal Year End

The following table provides certain information concerning the outstanding equity awards for each named executive officer as of December 31, 2021:

	Option Awards						Sto
Name	Number of Securities Underlying Unexercised Options/ Warrants (#) Exercisable	Number of Securities Underlying Unexercised Options/ Warrants (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/ Warrant Exercise Price ($)	Option/ Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value Shares or Uni of Stock Tha Have Not Vested ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Kevin A. Richardson, II	115,000(1)	-	-	$ 0.35	02/21/2023	-	
Chairman of the Board and Chief Executive Officer (principal executive officer)	452,381(3)	-	-	$ 0.11	10/1/2025	-	
	297,619(3)	-	-	$ 0.06	10/1/2025	-	
	700,000(4)	-	-	$ 0.04	6/16/2026	-	
	594,300(5)	-	-	$ 0.18	11/9/2026	-	
	900,000(6)	-	-	$ 0.11	6/14/2027	-	
	1,100,000(7)	-	-	$ 0.21	9/20/2028	-	
	50,000(9)	-	-	$ 0.15	8/26/2029	-	
Lisa E. Sundstrom	65,000(1)	-	-	$ 0.35	02/21/2023	-	
Chief Financial Officer (principal financial officer)	25,000(2)	-	-	$ 0.55	5/7/2024	-	
	301,587(3)	-	-	$ 0.11	10/1/2025	-	

	198,413[3]	-	-	$	0.06	10/1/2025	-
	500,000[4]	-	-	$	0.04	6/16/2026	-
	424,500[5]	-	-	$	0.18	11/9/2026	-
	600,000[6]	-	-	$	0.11	6/14/2027	-
	750,000[7]	-	-	$	0.21	9/20/2028	-
	50,000[9]	-	-	$	0.15	8/26/2029	-
Peter Stegano	333,644[1]	-	-	$	0.35	02/21/2023	-
Chief Operating Officer	50,000[2]	-	-	$	0.55	5/7/2024	-
	301,587[3]	-	-	$	0.11	10/1/2025	-
	198,413[3]	-	-	$	0.06	10/1/2025	-
	500,000[4]	-	-	$	0.04	6/16/2026	-
	424,500[5]	-	-	$	0.18	11/9/2026	-
	600,000[6]	-	-	$	0.11	6/14/2027	-
	750,000[7]	-	-	$	0.21	9/20/2028	-
	50,000[9]	-	-	$	0.15	8/26/2029	-

(1) On February 21, 2013, the company, by mutual agreement with all active employees and directors of the Company, cancelled options granted to the active employees and directors in the year ended December 31, 2011 and prior. In exchange for these options, the active employees and directors received new options to purchase shares of common stock at an exercise price of $0.35 per share. The Company cancelled all options which were previously granted to Mr. Richardson, Ms. Sundstrom and Mr. Stegagno. The Company granted Mr. Richardson 115,000 options, Ms. Sundstrom 65,000 options and Mr. Stegagno 334,644 options on February 21, 2013 which vest one-third at grant date, one-third on February 21, 2014 and one-third on February 21, 2015.

(2) The Company granted Ms. Sundstrom 25,000 and Mr Stegagno 50,000 options on May 7, 2014 which vests one-third at grant date, one-third on May 7, 2015 and one-third on May 7, 2016.

(3) The Company granted Mr. Richardson 750,000 options, Ms. Sundstrom 500,000 options and Mr. Stegagno 500,000 options on October 1, 2015 which vests at grant date.

(4) The Company granted Mr. Richardson 700,000 options, Ms. Sundstrom 500,000 options and Mr. Stegagno 500,000 options on June 16, 2016 which vests at grant date.

(5) The Company granted Mr. Richardson 594,300 options, Ms. Sundstrom 424,500 options and Mr. Stegagno 424,500 options on November 9, 2016 which vests at grant date.

(6) The Company granted Mr. Richardson 900,000 options, Ms. Sundstrom 600,000 options and Mr. Stegagno 600,000 options on June 15, 2017 which vests at grant date.

(7) The Company granted Mr. Richardson 1,100,000 options, Ms. Sundstrom 750,000 options and Mr. Stegagno 750,000 options on September 20, 2018 which vests at grant date.

(8) The Company granted 50,000 options each to Mr. Richardson, Ms. Sundstrom and Mr. Stegagno on August 26, 2019 which vests at grant date.

Director Compensation Table for Fiscal Year 2021

No fees or awards were given to directors for the year ended December 31, 2021

Discussion of Director Compensation

Effective January 1, 2018, the Company began to compensate its directors at an annual rate of $40,000 each. On August 26, 2019, the Company issued an option to purchase 50,000 shares of the Company's common stock at $0.15 per share to employee director Kevin A. Richardson II and to non-employee directors John F. Nemelka, Alan L. Rubino, A. Michael Stolarski and Maj-Britt Kaltoft. On September 20, 2018, the Company issued an option to purchase 1,100,000 shares of the Company's common stock at $0.21 per share to non-employee director Kevin A. Richardson II and the Company issued options to purchase 350,000 shares of the Company's common stock at $0.21 per share to non-employee directors John F. Nemelka, Alan L. Rubino, A. Michael Stolarski and Maj-Britt Kaltoft. On June 15, 2017, the Company issued an option to purchase 900,000 shares of the Company's common stock at $0.11 per share to non-employee director Kevin A. Richardson II and the Company issued options to purchase 300,000 shares of the Company's common stock at $0.11 per share to non-employee directors John F. Nemelka, Alan L. Rubino, A. Michael Stolarski and Maj-Britt Kaltoft. On November 9, 2016, the Company issued an option to purchase 594,300 shares of the Company's common stock at $0.18 per share to director Kevin A. Richardson, II and the Company issued options to purchase 169,800 shares of the Company's common stock at $0.18 per share to directors John F. Nemelka, Alan L. Rubino and A. Michael Stolarski. On June 16, 2016, the Company issued an option to purchase 700,000 shares of the Company's common stock at $0.04 per share to director Kevin A. Richardson, II and the Company issued options to purchase 200,000 shares of the Company's common stock at $0.04 per share to directors John F. Nemelka, Alan L. Rubino and A. Michael Stolarski. On October 1, 2015, the Company issued an option to purchase 452,381 shares of the Company's common stock at $0.11 per share and an option to purchase 297,619 shares of the Company's common stock at $0.50 per share to director Kevin A. Richardson, II and the Company issued options to purchase 150,795 shares of the Company's common stock at $0.11 per share and options to purchase 99,205 shares of the Company's common stock at $0.50 per share to directors John F. Nemelka and Alan L. Rubino. The options above issued at $0.50 per share were re-priced to $0.06 per share in March 2016 as the result of the public offering. On September 3, 2013, the Company issued an option to purchase 100,000 shares of the Company's common stock at $0.65 per share to director Alan L. Rubino. On February 21, 2013, the Company, by mutual agreement with all the active employees and directors of the Company, cancelled options granted to the active employees and directors in the year ended December 31, 2011 and prior. In exchange for these options, the active

employees and directors received new options to purchase shares of common stock at an exercise price of $0.35 per share. Kevin A. Richardson, II, and John F. Nemelka, each cancelled options to purchase 15,000 shares of the Company's Common Stock and were each issued options to purchase 115,000 shares of the Company's Common Stock at an exercise price of $0.35 per share.

The following are the aggregate number of option awards outstanding that have been granted to each of our non-employee directors as of December 31, 2021: Kevin A. Richardson, II – 4,209,300, John F. Nemelka – 1,434,800, Alan L. Rubino – 1,419,800, A. Michael Stolarski – 1,069,800 and Maj-Britt Kaltoft – 700,000

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

The following table sets forth certain information, as of December 31, 2021, 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 Shares Beneficially Owned	Percent of Shares Outstanding (2)
A. Michael Stolarski (3)	18,331,290	3.8%
Kevin A. Richardson II (4)	16,795,993	3.5%
Peter Stegagno (5)	4,418,007	0.9%
Iulian Cioanta (6)	3,636,146	0.8%
Lisa E. Sundstrom (7)	3,364,500	0.7%
John F. Nemelka (8)	1,696,055	0.4%
Alan Rubino	1,669,800	0.3%
Maj-Britt Kaltoft	950,000	0.2%
Thomas Price	450,000	0.1%
All directors and executive officers as a group (6 persons)	51,311,791	10.7%

(1) Unless otherwise noted, each beneficial owner has the same address as us.

(2) Applicable percentage ownership is based on 481,619,621 shares of common stock outstanding as of September 30, 2021, "Beneficial ownership" includes shares for which an individual, directly or indirectly, has or shares voting or investment power, or both, and also includes options that are exercisable within 60 days of September 30, 2021. Unless otherwise indicated, all of 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) Includes options to purchase up to 1,319,800 shares of common stock.

(4) Includes options to purchase up to 7,459,300 shares of common stock. In addition, this amount includes 1,324,723 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.

(5) Consists of options to purchase up to 3,658,144 shares of common stock.

(6) Consists of options to purchase up to 3,620,741 shares of common stock.

(7) Consists of options to purchase up to 3,364,500 shares of common stock.

(8) Includes options to purchase up to 1,684,800 shares of common stock.

Securities Authorized for Issuance Under Equity Compensation Plans

Information on securities authorized for issuance under the Company's equity compensation plans can be found in Item 5 under the same caption in this Annual Report on Form 10-K.

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

Related Party Transactions

Other than as described below, since January 1, 2021, there have been no transactions with related persons required to be disclosed in this report.

On August 6, 2020, the Company terminated that certain line of credit agreement with A. Michael Stolarski, a member of the Company's board of directors, dated December 29, 2017 and as amended November 12, 2018, in the amount of $1,000,000. As consideration for the termination of the Stolarski Line of Credit, the Company issued to A. Michael Stolarski a convertible promissory note in the principal amount of $223,511.

The Stolarski Note has a maturity date of August 6, 2021 and accrues interest at a rate equal to 12.0% per annum. In the event that the Stolarski Note has not been repaid prior to January 1, 2021, the holder may elect to convert the outstanding principal amount plus any accrued by unpaid interest thereon into shares of Common Stock at a conversion price of $0.10 per share.

In March 2021, PSWC paid the Company $125 thousand as a deposit for future purchase of new medical equipment.

On July 1, 2021, the Company purchased unused DermaPace 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.

Also, effective July 1, 2021, the Company entered into a short-term equipment rental agreement with PSWC, whereby the Company obtained DermaPace equipment from PSWC for $3,600 per month. The Company recorded $99 thousand in revenue from this arrangement.

October 2021 Advance from Director – On October 27, 2021 the Company received $25 thousand from A. Michael Stolarski (the "Stolarski Advance"). In exchange for the Stolarski Advance, as well as the $125 thousand deposit received in March 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.

Director Independence

Our board of directors has determined that 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.

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 for the years ended December 31, 2021 and December 31, 2020:

Fee Category	2021	2020
Audit fees	$ 450,000	$ 309,000
Tax fees	25,000	11,000
Audit related fees	-	-
All other fees	-	-
Total fees	$ 475,000	$ 320,000

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 board of directors evaluates 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 Form 8-K filed with the SEC on September 30, 2009).
3.1	Articles of Incorporation (Incorporated by reference 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 Appendix A to the Definitive Schedule 14C filed with the SEC on April 16, 2012).
3.4	Bylaws (Incorporated by reference 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 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 the Form 10-K filed with the SEC on March 30, 2016).
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock of the Company dated January 12, 2016 (Incorporated by reference to the Form 8-K filed with the SEC on January 19, 2016).
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock of the Company dated January 31, 2020 (Incorporated by reference to the Form 8-K filed with the SEC on February 6, 2020).
3.9	Certificate of designation of Series C Convertible Preferred Stock. (Incorporated by reference 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 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 the Form 8-K filed with the SEC on January 5, 2021).
4.1	Form of Class A Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.2	Form of Class B Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on September 30, 2009).
4.3	Form of Class D Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on October 14, 2010).

4.4	Form of Class E Warrant Agreement (Incorporated by reference to Form 8-K filed with the SEC on April 7, 2011).
4.5	Form of Series A Warrant (Incorporated by reference 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.
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	Warrant issued to Leviston Resources, LLC, dated April 20, 2021. (Incorporated by reference to the Form 8-K filed with the SEC on April 27, 2021).
4.28	Future Advance Convertible Promissory Note issued to Leviston Resources, LLC, dated April 2020, 2021. (Incorporated by reference to the Form 8-K filed with the SEC on April 27, 2021).
4.29	For of Warrant Issued September 3, 2021. (Incorporated by reference to the Form 8-K filed with the SEC on September 13, 2021).
4.30	Form of Future Advance Convertible Promissory Note Issued September 3, 2021. (Incorporated by reference to the Form 8-K filed with the SEC on September 13, 2021).
4.31	Secured Promissory Note issued to NH Expansion Credit Fund Holdings L.P., dated February 24, 2022. (Incorporated by reference to the Form 8-K filed with the SEC on March 2, 2022).
4.32	Amended and Restated Warrant issued to NH Expansion Credit Fund Holdings L.P., dated February 25, 2022. (Incorporated by reference to the Form 8-K filed with the SEC on March 2, 2022).
10.1∞	Amended and Restated 2006 Stock Option Incentive Plan of SANUWAVE Health, Inc. (Incorporated by reference to 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 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 the Form 8-K filed with the SEC on March 18, 2014).
10.4	Form of Subscription Agreement for the 18% Convertible Promissory Notes between the Company and the accredited investors a party thereto (Incorporated by reference 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 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 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 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 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 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 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 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 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 Form 8-K filed with the SEC on August 4, 2017).
10.14#	Binding Term Sheet for Joint Venture Agreement between the Company and MundiMed Distribuidora Hospitalar LTDA effective as of September 25, 2017 (Incorporated by reference to 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 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 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 dermaPACE 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 the Form 8-K filed with the SEC on September13, 2021).
10.47	Form of Registration Rights Agreement Entered into September 3, 2021. (Incorporated by reference to the Form 8-K filed with the SEC on September 13, 2021).
10.48	Form of Security Agreement. (Incorporated by reference 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 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 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.
10.56*	Future Receivables Agreement by and between GCF Resources, LLC and SANUWAVE Health, Inc. dated December 22, 2021.
10.57*	Form of Security Agreement and Guarantee by and between GCF Resources, LLC and SANUWAVE Health, Inc. dated December 22, 2021.
14.1	Code of Business Conduct and Ethics of SANUWAVE Health, Inc. (Incorporated by reference to the Form 10-K filed with the SEC on March 30, 2016).
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned hereunto duly authorized.

SANUWAVE HEALTH, INC.

Dated: May 13, 2022

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 Lisa E. Sundstrom, 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)	May 13, 2022
By: /s/ *Lisa E. Sundstrom* Name: Lisa E. Sundstrom	Chief Financial Officer (principal financial and accounting officer)	May 13, 2022
By: */s/ A. Michael Stolarski* Name: A. Michael Stolarski	Director	May 13, 2022
By: */s/ Jeff Blizard* Name: Jeff Blizard	Director	May 13, 2022
By: */s/ Ian Miller* Name: Ian Miller	Director	May 13, 2022
By: */s/ Jim Tyler* Name: Jim Tyler	Director	May 13, 2022

EXHIBIT 21.1

List of Subsidiaries

Direct Subsidiary of SANUWAVE Health, Inc.

1. SANUWAVE, Inc., a Delaware corporation

Subsidiaries of SANUWAVE, Inc. – Indirect Subsidiaries of SANUWAVE Health, Inc.

1. SANUWAVE Services, LLC, a Delaware limited liability company

1. SANUWAVE AG, a company organized under the laws of Switzerland

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of SANUWAVE Health, Inc. on Form S-8 (File No. 333-170301) of our report dated May 13, 2022, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of SANUWAVE Health, Inc. as of December 31, 2021 and 2020 and for each of the two years in the period ended December 31, 2021, which report is included in this Annual Report on Form 10-K of SANUWAVE Health, Inc. for the year ended December 31, 2021.

/s/ Marcum LLP

Marcum LLP
New York, NY
May 13, 2022

EXHIBIT 31.1

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Kevin A. Richardson, II, certify that:

1. I have reviewed this Annual Report on Form 10-K of SANUWAVE Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2022

/s/ *Kevin A. Richardson, II*
Kevin A. Richardson, II
Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

Certification of Chief Financial Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Lisa E. Sundstrom, certify that:

1. I have reviewed this Annual Report on Form 10-K of SANUWAVE Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2022

/s/ *Lisa E. Sundstrom*
Lisa E. Sundstrom
Chief Financial Officer
(principal financial and accounting officer)

EXHIBIT 32.1

CERTIFICATION

In connection with the annual report of SANWUAVE Health, Inc. (the "Company") on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Kevin A. Richardson, II, Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: May 13, 2022

/s/ *Kevin A. Richardson, II*
Kevin A. Richardson, II
Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION

In connection with the annual report of SANUWAVE Health, Inc. (the "Company") on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Lisa E. Sundstrom, Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: May 13, 2022

/s/ Lisa E. Sundstrom
Lisa E. Sundstrom
Chief Financial Officer

EXHIBIT 10.55

December 21st, 2021

Attn: KEVIN A RICHARDSON
SANUWAVE, INC

ML Factors agrees to refinance the remaining RTR balance due in the amount of $651,190.00 from your previous GCF contracts dated and signed on September 27, 2021.

This RTR balance will be reduced from the disbursement amount of $1,500,000.00 on the new GCF agreement, dated December 21st, 2021. Please affix your signature below to confirm your acknowledgement of this transaction.

Thank you,
GCF Resources

X Kevin A Richardson II Date 12/22/2021

December 21st, 2021

ATTN: KEVIN A RICHARDSON II

In regards to SANUWAVE, INC. (the “merchant”), GCF Resources agrees that if the merchant pays back $1,770,000.00 within 30 days of funding the advance will be paid in full. Additionally, if the merchant pays back $1,815,000.00 within 31-60 days of funding the advance will be considered paid in full. Finally, if the merchant pays back $1,875,000.00 with.in 61-90 days of funding the advance will be considered paid in full.

By signing below, you acknowledge and agree to this adjustment.
Thank you.

GCF Resources

X Kevin A Richardson II Date 12/22/2021

456A Central Avenue #129, Cedarhurst, NY 11516

December 21, 2021

In regards to [Sanuwave, Inc] (the “merchant”), GCF RESOURCES LLC provides this addendum to confirm that the first 6 payments will be $59,000.00 per week, beginning January 3rd 2022, and starting week 7 the new payment amount will be $98,666.67, which will continue to be debited on a weekly basis until the contract is paid in full.

Thank you

X Kevin A Richardson II — 12/22/2021

Print Name — Date

X Kevin A Richardson II — 12/22/2021

Signature — Date

EXHIBIT 10.56

FUTURE RECEIVABLES AGREEMENT

This FUTURE RECEIVABLES AGREEMENT (this "Agreement"), dated December 16, 2021, is made by and between GCF Resources LLC, ("GCF") and **SANUWAVE, INC.** ("Merchant)".

Merchant's Legal Name: SANUWAVE, INC.
DBA Name: SANUWAVE
Legal Entity: Corporation
Address: 3360 MARTIN FARM RD #100 City: SUWANEE State: GA Zip: 30024

PURCHASE AND SALE OF FUTURE RECEIVABLES

Merchant hereby sells, assigns and transfers to GCF (making GCF the absolute owner) in consideration of the purchase price specified below (the Purchase Price) , the specified percentage specified below (the Specified Percentage) of all of Merchant's future accounts, contract rights and other entitlements arising from or relating to the payment of monies from Merchant's customers 'and/or other third party payors (collectively, the "Receipts", including all payments made by cash, check, electronic transfer or other form of monetary payment in the ordinary course of the Merchant's business), for the payments due to Merchant as a result of Merchant's sale of goods or services (the "Transactions") until the receipts purchased amount specified below (the Purchased Amount) has been delivered by or on behalf of Merchant to GCF. Merchant hereby acknowledges and agrees that GCF may elect, in its sole discretion, to pay to Merchant a percentage of the full Purchase Price specified below. If GCF elects to pay to Merchant less than the full Purchase Price specified below then the amount actually paid by GCF shall be deemed the Purchase Price for purposes of this transaction notwithstanding the Purchase Price specified below and the Purchased Amount shall automatically be reduced proportionately notwithstanding the Purchased amount specified below. By signing this Agreement , Merchant expressly consents to be bound to the terms of this Agreement whether GCF, in its sole discretion, elects to pay the full Purchase Price specified below or a percentage thereof. Merchant further acknowledges that if GCF elects to pay a percentage of the full Purchase Price specified below, that such payment shall not be deemed a default under this Agreement, and that all other terms and conditions, specifically including but not limited to the Daily Amount, shall remain in effect except as otherwise provided herein. The Purchased Amount shall be paid to GCF by...in consideration of the purchase price specified below (the Purchase Price), the specified percentage specified below (the Specified Percentage) of all of Merchants...until the receipts purchased amount specified below (the Purchased Amount) has been delivered by or on behalf of Merchant to GCF. Merchant hereby acknowledges and agrees that GCF may elect, in its sole discretion, to pay to Merchant a percentage of the full Purchase Price specified below. If GCF elects to pay to Merchant less than the full Purchase Price specified below then the amount actually paid by GCF shall be deemed the Purchase Price for purposes of this transaction notwithstanding the Purchase Price specified below and the Purchased Amount shall automatically be reduced proportionately notwithstanding the Purchased Amount specified below. By signing this Agreement, Merchant expressly consents to be bound to the terms of this Agreement whether GCF, in its sole discretion, elects to pay the full Purchase Price specified below or a percentage thereof. Merchant further acknowledges that if GCF elects to pay a percentage of the full Purchase Price specified below, that such payment shall not be deemed a default under this Agreement, and that all other terms and conditions, specifically including but not limited to the Daily Amount, shall remain in effect except as otherwise provided herein. The Purchased Amount shall be paid to GCF by...paid to GCF by Merchant's irrevocably directing and authorizing that there be only one depositing bank account, which account must be acceptable to, and pre-approved by, GCF (the "Account") into which Merchant and Merchants customers shall remit the Specified Percentage of the Merchants settlement amounts due from each Transaction, until such time as GCF receives payment in full of the Purchased Amount. Merchant hereby authorizes GCF to ACH Debit the Daily Amount (as specified below) from the Merchants Account on a daily basis and will provide GCF with all required access codes, and monthly bank statements. Merchant understands that it is responsible for ensuring that the specified percentage to be debited by GCF remains in the Account and will be held responsible for any fees incurred by GCF resulting from a rejected ACH attempt or an event of default. (See Appendix A) GCF is not responsible for any overdrafts or rejected transactions that may result from GCF ACH debiting the specified amounts under the terms of this agreement. GCF will debit the specific daily amount each business day. The Merchant shall deliver to GCF, no later than the 18th date of each month the bank statement for the Account in respect of the immediately preceding month. Within three business days of GCF receipt of the Merchants monthly bank statements, GCF shall reconcile the Merchants Account by either crediting or debiting the difference from or back to the Merchants Account so that the amount debited per month equals the Specified Percentage. If the Merchant fails to deliver the bank statement for the Account for any month, GCF shall consider that the specific remittances were equal to the Specified Percentage of the settlement amount due from each Transaction for such month. GCF may, upon Merchants request, adjust the amount of any payment due under this Agreement at GCF sole discretion and as it deems appropriate. Notwithstanding anything to the contrary in this Agreement or any other agreement between GCF and Merchant, upon the violation of any provision contained in Section 1.11 of the MERCHANT AGREEMENT TERMS AND CONDITIONS or the occurrence of an Event of Default under Section 3 of

the MERCHANT AGREEMENT TERMS AND CONDITIONS, the Specified percentage shall equal 100%. A list of all fees applicable under this Agreement is contained in Appendix A. For the avoidance of any doubt, each party to this Agreement acknowledges, agrees and understands that the transaction contemplated by this Agreement is a purchase and sale of future receivables and not a loan, and no party hereto intends for this Agreement to be, or to be deemed to be, a loan agreement. Accordingly, there is no interest payable hereunder and no mandated date on which amounts hereunder are due. furthermore, the failure of the Merchant to make sales and the Merchant going out of business or bankrupt is, in and of itself, not an Event of Default under this Agreement. These are risks assumed by GCF. Neither the Merchant nor any affiliate of the Merchant, directly or indirectly, shall assert or attempt to assert at any time and in any forum that this Agreement is a loan agreement or that the transactions contemplated hereby are or should be characterized as loans.

Purchase Price	**Specified Percentage**	**Estimated Daily Amount**	**Receipts Purchased Amount**
$1,500,000.00	10%	$17,750.00	$2,130,000.00

THE TERMS AND CONDITIONS, THE “SECURITY AGREEMENT AND GUARANTY” AND THE “AUTHORIZATION AGREEMENT” ATTACHED HERETEO, ARE All HEREBY INCORPORATED IN AND MADE A PART OF THIS AGREEMENT.

MERCHANT

BY: KEVIN A RICHARDSON II **X** Kevin A Richardson II 12/22/2021
(SIGNATURE)

CEO #1: KEVIN A RICHARDSON II **X** Kevin A Richardson II
(SIGNATURE) (DATE)

CEO #2: **X** _____ _____
(SIGNATURE) (DATE)

GCF Resources LLC
BY: **X** _____
(COMPANY OFFICER) (SIGNATURE)

TERMS AND CONDITIONS

I. TERMS OF ENROLLMENT IN PROGRAM

1.1 Merchant Deposit Agreement. Merchant shall execute an agreement (the "Merchant Deposit Agreement") acceptable to GCF with a Bank acceptable to GCF to obtain electronic fund transfer services for the Merchant's account at the Bank approved by GCF (the "Account"). Merchant shall provide GCF and/or its authorized agent(s) with all of the information authorizations and passwords necessary for verifying Merchant's receivables'. receipts, deposits and withdrawals into and from the Account. Merchant hereby authorizes GCF and/or its agent(s) to deduct from the Account the amounts owed to GCF for the receipts as specified herein and to pay such amounts to GCF. Merchant also hereby authorizes GCF to withdraw from the Account the specified percentages and/or sums by GCF debiting the account. These authorizations apply not only to the approved Account but also to any subsequent or alternate account used by the Merchant for these deposits, whether pre-approved by GCF or not. This additional authorization is not a waiver of GCF entitlement to declare this Agreement breached by Merchant as a result of its usage of an account that GCF did not first pre-approve in writing prior to Merchant's usage thereof. The aforementioned authorizations shall be irrevocable without the written consent of GCF.

1.2 Term of Agreement. This Agreement shall remain in full force and effect until the entire "Purchased Amount" is received by GCF as per the terms of this Agreement, however, at any point during the term of this Agreement, Merchant may terminate this Agreement upon ninety days 'prior written notice (effective upon actual receipt) to GCF. The termination of this Agreement shall not affect Merchant's continuing obligation and responsibility to fully satisfy all outstanding obligations that are due to GCF simultaneous with the Notice of termination.

1.3 Future Purchases. GCF reserves the right to rescind the offer to make any purchase payments hereunder, in its sole and absolute discretion.

1.4 Financial Condition. Merchant and Guarantor(s) (as hereinafter defined and limited) authorize GCF and its agents to investigate their financial responsibility and history, and will provide to GCF any authorizations, bank or financial statements, tax returns, etc., as GCF deems necessary in its sole and absolute discretion prior to or at any time after execution of this Agreement. A photocopy of this authorization will be deemed as acceptable as an authorization for release of financial and credit reporting information. GCF is authorized to update such information and financial and credit profiles from time to time as it deems appropriate.

1.5 Transactional History. Merchant authorizes all of their banks and brokers to provide GCF with Merchant's banking, brokerage and/or processing history to determine qualification or continuation in this program.

1.10 Power of Attorney. Merchant irrevocably appoints GCF as its agent and attorney in fact with full authority to take any action or execute any instrument or document to settle all obligations due to GCF from Processor, or in the case of a violation by Merchant of Section 1.12 or the occurrence of an Event of Default under Section 3.1 hereof, from Merchant, under this Agreement, including without limitation (i) to obtain and adjust insurance; {ii) to collect monies due or to become due under or in respect of any of the Collateral; (iii) to receive, endorse and collect any checks, notes, drafts, instruments, documents or chattel paper in connection with clause (i) or clause (ii) above; (iv) to sign Merchant's name on any invoice, bill of lading, or assignment directing customers or account debtors to make payment directly to GCF; and (v) to file any claims or take any action or institute any proceeding which GCF may deem necessary for the collection of any of the unpaid Purchased Amount from the Collateral, or otherwise to enforce its rights with respect to payment of the Purchased Amount. In connection therewith, all costs, expenses and fees, including legal fees, shall be payable by and from Merchant, and GCF is authorized to use Merchant's funds to pay for the same.

1.11 Protections against Default. The following Protections 1 through 7 may be invoked by GCF immediately and without notice to Merchant in the event: (a) Merchant takes any action to discourage the use of electronic check processing that are settled through Processor, or permits any event to occur that could have an adverse effect on the use, acceptance, or authorization of checks or other payments or deposits for the purchase of Merchant's services and products including but not limited to direct deposit of any checks into a bank account without scanning into the GCF electronic check processor; (b) Merchant changes its arrangements with Processor in any way that is adverse or unacceptable to GCF; (c) Merchant changes the electronic check processor through which the Receipts are settled from Processor to another electronic check processor, or permits any event to occur that could cause diversion of any of Merchant's check or deposit transactions to another processor; (d) Merchant interrupts the operation of this business (other than adverse weather, natural disasters or acts of God) transfers, moves, sells, disposes, or otherwise conveys its business and/or assets without (i) the express prior written consent of GCF, and (ii) the written agreement of any purchaser or transferee to the assumption of all of Merchant's obligations under this Agreement pursuant to documentation satisfactory to GCF; or (e) Merchant takes any action, fails to take any action, or offers any incentive economic or otherwise-the result of which will be to induce any customer or customers to pay for Merchant's services with any means other than payments, checks or deposits that are settled through Processor. These protections are in addition to any other remedies available to GCF at law, in equity or otherwise pursuant to this Agreement.

Protection 1. The full uncollected Purchase Amount plus all *fees* (including legal fees) due under this Agreement and the attached Security Agreement become due and payable in full immediately. *Protection 2* . GCF may enforce the provisions of the Personal Guaranty of Performance against the Guarantor(s). *Protection*

1.6 Indemnification. Merchant and Guarantor(s) jointly and severally indemnify and hold harmless Processor, its officers, directors and shareholders against all losses, damages, claims, liabilities and expenses (including reasonable attorney's fees) incurred by Processor resulting from (a) claims asserted by GCF for monies owed to GCF from Merchant and (b) actions taken by Processor in reliance upon any fraudulent, misleading or deceptive information or instructions provided by GCF.

1.7 No Liability. In no event will GCF be liable for any claims asserted by Merchant or Guarantors under any legal theory for lost profits, lost revenues, lost business opportunities, exemplary, punitive, special, incidental, indirect or consequential damages, each of which is waived by both Merchant and Guarantor(s). In the event these claims are nonetheless raised, Merchant and Guarantors will be jointly liable for all of GCF legal fees and expenses resulting there from.

1.8 Reliance on Terms. Section 1.1, 1.7, 1.8 and 2.5 of this Agreement are agreed to for the benefit of Merchant, GCF and Processor, and notwithstanding the fact that Processor is not a party of this Agreement, Processor may rely upon their terms and raise them as a defense in any action .

1.9 Sale of Receipts. Merchant and GCF agree that the Purchase Price under this Agreement is in exchange for the Purchased Amount, and that such Purchase Price is not intended to be, nor shall it be construed as a loan from GCF to Merchant. Merchant agrees that the Purchase Price is in exchange for the Receipts pursuant to this Agreement, and that it equals the fair market value of such Receipts. GCF has purchased and shall own all the Receipts described in this Agreement up to the full Purchased Amount as the Receipts are created. Payments made to GCF in respect to the full amount of the Receipts shall be conditioned upon Merchant's sale of products and services, and the payment therefore by Merchant's customers in the manner provided in Section 1.1. In no event shall the aggregate of all amounts or any portion thereof be deemed as interest hereunder, and in the event it is found to be interest despite the parties hereto specifically representing that it is NOT interest , it shall be found that no sum charged or collected hereunder shall exceed the highest rate permissible at law. In the event that a court nonetheless determines that GCF has charged or received interest hereunder in excess of the highest applicable rate, the rate in effect hereunder shall automatically be reduced to the maximum rate permitted by applicable law and GCF shall promptly refund to Merchant any interest received by GCF in excess of the maximum lawful rate, it being intended that Merchant not pay or contract to pay, and that GCF not receive or contract to receive, directly or indirectly in any manner whatsoever, interest in excess of that which may be paid by Merchant under applicable law. As a result thereof , Merchant knowingly and willingly waives the defense of Usury in any action or proceeding.

3. Merchant hereby authorizes GCF to execute in the name of the Merchant a Confession of Judgment in favor of GCF in the amount of Purchase Amount stated in the Agreement. Upon breach of any provision in this paragraph 1.11, GCF may enter that Confession of Judgment as a Judgment with the Clerk of any Court and execute thereon. *Protection 4.* GCF may enforce its security interest in the Collateral identified in the attached Security Agreement and Guarantee. *Protection 5.* The entire Purchase Amount and all fees (including legal fees) shall become immediately refundable and payable to GCF from Merchant. *Protection 6.* GCF may proceed to protect and enforce its rights and remedies by lawsuit. In any such lawsuit, under which GCF shall recover Judgment against Merchant, Merchant shall be liable for all of GCF costs of the lawsuit, including but not limited to all reasonable attorneys 'fees and court costs. *Protection* 7. This Agreement shall be deemed Merchants Assignment of Merchant's Lease of Merchant's business premises to GCF. Upon breach of any provision in this Agreement, GCF may exercise its rights under this Assignment of Lease without prior Notice to Merchant. *Protection 8.* GCF may debit Merchant's depository accounts wherever situated by means of ACH debit or facsimile signature on a computer generated check drawn on Merchant's bank account or otherwise for all sums due to GCF.

1.12 Protection of Information. Merchant and each person signing this Agreement on behalf of Merchant and/or as Owner or Guarantor, in respect of himself or herself personally, authorizes GCF to disclose information concerning Merchant's and each Owner's and each Guarantor's credit standing (including credit bureau reports that GCF obtains) and business conduct only to agents, affiliates, subsidiaries, and credit reporting bureaus. Merchant and each Owner and each Guarantor hereby and each waives to the maximum extent permitted by law any claim for damages against GCF or any of its affiliates relating to any (i) investigation undertaken by or on behalf of GCF as permitted by this Agreement or (ii) disclosure of information as permitted by this Agreement .

1.13 Confidentiality. Merchant understands and agrees that the terms and conditions of the products and services offered by GCF, including this Agreement and any other GCF documentations (collectively, "Confidential Information ") are proprietary and confidential information of GCF. Accordingly unless disclosure is required by law or court order, Merchant shall not disclose Confidential Information of GCF to any person other than an attorney, accountant, financial advisor or employee of Merchant who needs to know such information for the purpose of advising Merchant ("Advisor"), provided such Advisor uses such information solely for the purpose of advising Merchant and first agrees in writing to be bound by the terms of this section. A breach hereof entitles GCF to not only damages and legal fees but also to both a Temporary Restraining Order and a Preliminary Injunction without Bond or Security.

1.14 Publicity. Merchant and each of Merchant's Owners and all Guarantors hereto all hereby authorizes GCF to use its, his or her name in listings of clients and in advertising and marketing materials.

1.15 D /B /A's. Merchant hereby acknowledges and agrees that GCF may be using "doing business as" or "d/b/a" names in connection with various matters relating to the transaction between GCF and Merchant, including the filing of UCC-1 financing statements and other notices or filings.

II. REPRESENTATIONS, WARRANTIES AND COVENANTS

Merchant represents warrants and covenants that, as of this date and during the term of this Agreement; and until GCF is fully paid:

2.1 Financial Condition and Financial Information. Merchant's and Guarantors 'bank and financial Statements, copies of which have been furnished to GCF, and future statements which will be furnished hereafter at the discretion of GCF, fairly represent the financial condition of Merchant at such dates, and since those dates there has been no material adverse changes, financial or otherwise, in such condition, operation or ownership of Merchant. Merchant and Guarantors have a continuing, affirmative obligation to advise GCF of any material adverse change in their financial condition, operation or ownership. GCF may request statements at any time during the performance of this

2.8 Estoppel Certificate. Merchant will at every and all times, and from time to time, upon at least one (1) day's prior notice from GCF to Merchant, execute, acknowledge and deliver to GCF and/or to any other person, firm or corporation specified by GCF, a statement certifying that this Agreement is unmodified and in full force and effect (or, if there have been modifications, that the same is in full force and effect as modified and stating the modifications) and stating the dates which the Purchased Amount or any portion thereof has been repaid.

2.9 No Bankruptcy. As of the date of this Agreement, Merchant is not insolvent and does not contemplate and has not filed any petition for bankruptcy protection under Title 11 of the United States Code and there has been no involuntary petition brought or pending against Merchant. Merchant further warrants that it does not anticipate filing any such bankruptcy petition and it does not anticipate that an involuntary petition will be filed against it . In the event that the Merchant files for bankruptcy protection or is placed under an involuntary filing Protections 2 and 3 are immediately invoked.

2.10 Working Capital Funding. Merchant shall not enter into any arrangement, agreement or commitment that relates to or involves the Receipts, whether in the form of a purchase of, a loan against, collateral against or the sale or purchase of credits against, Receipts or future check sales with any party other than GCF.

2.11 Unencumbered Receipts. Merchant has good, complete, unencumbered and marketable title to all Receipts, free and clear of any and all liabilities, liens, claims, changes, restrictions, conditions, options, rights, mortgages, security interests, equities, pledges and encumbrances of any kind or nature whatsoever or any other rights or interests that may be inconsistent with the transactions contemplated with, or adverse to the interests of GCF.

2.12 Business Purpose. Merchant is a valid business in good standing under the laws of the jurisdictions in which it is organized and/or operates, and Merchant is entering into this Agreement for business purposes and not as a consumer for personal, family or household purposes.

2.13 Defaults under Other Contracts. Merchant's execution of, and/or performance under this Agreement, will not cause or create an event of default by Merchant under any contract with another person or entity.

2.14 Good Faith, Best Efforts and Due Diligence. Merchant and Guarantors hereby affirm that they will conduct the business in Good Faith and will expend their best efforts to maintain and grow its business, to ensure that GCF obtains the Purchased Amount. Furthermore, Merchant and Guarantors hereby agree, warrant and represent hereby that they will constantly perform all appropriate Due Diligence and credit checks of all of the customers 'finances, cash flow, solvency, good faith, payment histories and business reputations {the "Due Diligence Requirements") as may suffice to ensure any and all products and/or services provided, sold or delivered by Merchant to said customers will be paid for by customers in full and on time, and

Agreement and the Merchant and Guarantors shall provide them to GCF within S business days. Merchant's or Guarantors' failure to do so is a material breach of this Agreement.

2.2 Governmental Approvals. Merchant is in compliance and shall comply with all laws and has valid permits, authorizations and licenses to own , operate and lease its properties and to conduct the business in which it is presently engaged and/or will engage in hereafter.

2.3 Authorization. Merchant, and the person(s) signing this Agreement on behalf of Merchant, have full power and authority to incur and perform the obligations under this Agreement, all of which have been duly authorized.

2.4 Insurance. Merchant will maintain business-interruption insurance naming GCF as loss payee and additional insured in amounts and against risks as are satisfactory to GCF and shall provide GCF proof of such insurance upon request.

2.5 Electronic Check Processing Agreement. Merchant will not change its processor, add terminals, change its financial institution or bank account(s) or take any other action that could have any adverse effect upon Merchant's obligations under this Agreement, without GCF prior written consent. Any such changes shall be a mate rial breach of this Agreement.

2.6 Change of Name or Location. Merchant will not conduct Merchant's businesses under any name other than as disclosed to the Processor and GCF, nor shall Merchant change any of its places of business without prior written consent by GCF.

2.7 Daily Batch Out. Merchant will batch out receipts with the Processor on a daily basis.

will not result in the creation of an unpaid account. These Due Diligence Requirements must be performed prior to any sales to any customer, and repeated no less frequently than monthly for so long as any sums are due from those customers. Full documentation of all of Merchant's compliance with its Due Diligence Requirements must be maintained in Merchant's files so long as GCF has not fully collected all sums due to it. This is not a guaranty of payment by customers, but is a guaranty of full, adequate and good faith Due Diligent investigation and credit check of customers before extending credit to them and continuing no less frequently than monthly so long as sums are still due.

III. EVENTS OF DEFAULT AND REMEDIES

3.1 Events of Default. The occurrence of any of the following events shall constitute an "Event of Default" hereunder: {a) Merchant or Guarantor shall violate any term or covenant in this Agreement; (b) Any representation or warranty by Merchant in this Agreement shall prove to have been incorrect, false or misleading in any material respect when made; (c) the sending of notice of termination by Merchant; (d) Merchant shall transport, move, interrupt, suspend, dissolve or terminate its business; (e) Merchant shall transfer or sell all or substantially all of its assets; (f) Merchant shall make or send notice of any intended bulk sale or transfer by Merchant; (g) Merchant shall use multiple depository accounts without the prior written consent of GCF (h) Merchant shall change its depositing account without the prior written consent of GCF; (i) Merchant shall perform any act that reduces the value of any Collateral granted under this Agreement; or (j) Merchant shall default under any of the terms, covenants and conditions of any other agreement with GCF.

3.2 Personal Guaranty. In the event of a Default under Sections 2.3, 2.5, 2.6, 2.9, 2.10, 2.11, 2.12, 2.13, and 2.14 or upon the occurrence of Event Of Default as defined in Section 3.1, should GCF determine that the Purchased Amount cannot be obtained from the Merchant's business, GCF will enforce its rights against the Guarantors of this transaction. Said Guarantors **will** be jointly and severally liable to GCF for all of GCF losses and damages, in additional to all costs and expenses and legal fees associated with such enforcement.

3.3 Remedies. In case any Event of Default occurs and is not waived pursuant to Section 4.4.1 hereof, GCF may proceed to protect and enforce its rights or remedies by suit in equity of by action at law, or both, whether for the specific performance of any covenant, agreement or other provision contained herein, or to enforce the discharge of Merchant's obligations hereunder (including the Guaranty) or any other legal or equitable right or remedy. All rights, powers and remedies of GCF after the occurrence of an Event of Default, are cumulative and not exclusive and shall be in addition to any other rights, powers or remedies provided by law or equity. Simultaneous with the execution of this Agreement Merchant and Guarantor shall execute a Verified Confession of Judgment. In addition to the other remedies available to GCF upon any Event of Default, Merchant and Guarantor agree that GCF may file a Verified Confession of Judgment in New York (or an Agreed Judgment in Texas) without notice to Merchant and Guarantor and may seek to obtain a judgment for all amounts due and owing under this Agreement. In addition, GCF's remedies may include garnishment, or prejudgment garnishment, of Merchant's bank account .

3.4 Costs. Merchant shall pay to GCF all reasonable costs associated with (a) a breach by Merchant of the Covenants in this Agreement and the enforcement thereof, and (b) the enforcement of GCF remedies set forth in Section 4.2 below, including but not limited to court costs and attorneys 'fees.

3.5 Required Notifications. Merchant is required to give GCF written notice within 24 hours of any filing under Title 11 of the United States Code. Merchant is required to give GCF seven days 'written notice prior to the closing of any sale of all or substantially all of the Merchant's assets or stock.

IV. MISCELLANEOUS

4.1 Modifications: Agreements. No modification, amendment, waiver or consent of any provision of this Agreement shall be effective unless the same shall be in writing and signed by GCF.

4.2 Assignment. GCF may assign, transfer or sell its rights to receive the Purchased Amount or delegate its duties hereunder, either in whole or in part.

4.3 Notices. All notices, requests, consents, demands and other communications hereunder shall be delivered by certified mail, return receipt requested, to the respective parties to this Agreement at the addresses set forth in this Agreement. Notices to GCF shall become effective only upon receipt by GCF. Notices to Merchant shall become effective three days after mailing.

4.4 Waiver Remedies. No failure on the part of GCF to exercise, and no delay in exercising, any right under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any right under this Agreement preclude any other or further exercise thereof or the exercise of any other

4.6 Survival of Representation, etc. All representations, warranties and covenants herein shall survive the execution and delivery of this Agreement and shall continue in full force until all obligations under this Agreement shall have been satisfied in full and this Agreement shall have terminated.

4.7 Interpretation. All Parties hereto have reviewed this Agreement with attorney of their own choosing and have relied only on their own attorneys 'guidance and advice. No construction determinations shall be made against either Party hereto as drafter.

4.8 Severability. In case any of the provision in this Agreement is found to be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of any other provision contained herein shall not in any way be affected or impaired.

4.9 Entire Agreement. Any provision hereof prohibited by law shall be ineffective only to the extent of such prohibition, without invalidating the remaining provisions hereof. This Agreement and the Security Agreement, Guaranty and Confession of Judgment hereto constitute and embody the entire agreement between Merchant and GCF and supersede all prior agreements and understandings relating to the subject matter hereof.

4.10 JURY TRIAL WAIVER. THE PARTIES HERETO WAIVE TRIAL BY JURY IN ANY COURT IN ANY SUIT, ACTION OR PROCEEDING ON ANY MATTER ARISING IN CONNECTION WITH OR IN ANY WAY RELATED TO THE TRANSACTIONS OR THE ENFORCEMENT HEREOF. THE PARTIES HERETO ACKNOWLEDGE THAT EACH MAKES THIS WAIVER KNOWINGLY, WILLINGLY AND VOLUNTARILY AND WITHOUT DURESS, AND ONLY AFTER EXTENSIVE CONSIDERATION OF THE RAMIFICATIONS OF THIS WAIVER WITH THEIR ATTORNEYS.

4.11 CLASS ACTION WAIVER. THE PARTIES HERETO WAIVE ANY RIGHT TO ASSERT ANY CLAIMS AGAINST THE OTHER PARTY AS A REPRESENTATIVE OR MEMBER IN ANY CLASS OR REPRESENTATIVE ACTION, EXCEPT WHERE SUCH WAIVER IS PROHIBITED BY LAW AS AGAINST PUBLIC POLICY. TO THE EXTENT EITHER PARTY IS PERMITIED BY LAW OR COURT OF LAW TO PROCEED WITH A CLASS OR REPRESENTATIVE ACTION AGAINST THE OTHER, THE PARTIES HEREBY AGREE THAT: (1) THE PREVAILING PARTY SHALL NOT BE ENTITLED TO RECOVER ATTORNEYS FEES OR COSTS ASSOCIATED WITH PURSUING THE CLASS OR REPRESENTATIVE ACTION (NOTWITHSTANDING ANY OTHER PROVISION IN THIS AGREEMENT); AND (2) THE PARTY WHO INITIATES OR PARTICIPATES AS A MEMBER OF THE CLASS WILL NOT SUBMIT A CLAIM OR OTHERWISE PARTICIPATEIN ANY RECOVERY SECURED THROUGH THE CLASS OR REPRESENTATIVE ACTION.

right. The remedies provided hereunder are cumulative and not exclusive of any remedies provided by law or equity.

4.5 Binding Effect; Governing Law, Venue and Jurisdiction. This Agreement shall be binding upon and inure to the benefit of Merchant, GCF and their respective successors and assigns, except that Merchant shall not have the right to assign its rights hereunder or any interest herein without the prior written consent of GCF, which consent may be withheld in GCF 'sole discretion. GCF reserves the rights to assign this Agreement with, or without written notice to Merchant. This Agreement shall be governed by and construed exclusively in accordance with the laws of the State of New York, without regards to any applicable principles of conflicts of law. If there is any suit, action, litigation or proceeding arising hereunder, or for the interpretation, performance or breach hereof, by either party, then such litigation shall only be instituted in any court sitting in the state of New York or Texas (the "Acceptable Forums"). The parties, including Merchant and Guarantor, agree that the Acceptable Forums are a convenient forum and submit to personal jurisdiction of the Acceptable Forums and waive any and all objections to jurisdiction or venue. Should any proceeding be initiated in any other state or forum, the parties waive any right to oppose any motion or application made by either party to transfer such proceeding to the Acceptable Forums. Additionally, Merchant and Guarantor hereby agree to waive any formal personal service of process and agree that any summons and/or complaint or other process to commence any litigation by GCF will be properly served if sent by certified mail, return receipt requested to the mailing address listed on page 1 of this Agreement.

4.12 Facsimile & Digital Acceptance. Facsimile signatures and Electronic Digital signatures hereon shall be deemed acceptable for all purposes.

4.13 Stacking Fee. $5,000.00 - When Merchant takes additional funding after getting funded by GCF while Merchant has a balance with GCF or any subsidiary or any other GCF associated entities. In the event GCF is stacked by another funder, GCF has the right to collect an additional daily payment per day.

Merchant Initial _____

EXHIBIT 10.57

SECURITY AGREEMENT AND GUARANTEE

Merchant's Legal Name: SANUWAVE, INC.		**DBA Name: SANUWAVE**	
Address: 3360 MARTIN FARM RD #100	**City: SUWANEE**	**State: GA**	**Zip: 30024**
Federal Tax ID#: 20-3198616			

SECURITY AGREEMENT

Security Interest. This Agreement will constitute a security agreement under the Uniform Commercial Code. Merchant grants to GCF a security interest in and lien upon: (a) all accounts, chattel paper, documents, equipment, general intangibles, instruments, and inventory, as those terms are defined in Article 9 of the Uniform Commercial Code (the "UCC"), now or hereafter owned or acquired by Merchant, (b) all proceeds, as that term is defined in Article 9 of the UCC (c) all funds at any time in the Merchant's Account, regardless of the source of such funds, (d) present and future Electronic Check Transactions, and (e) any amount which may be due to GCF under this Agreement, including but not limited to all rights to receive any payments or credits under this Agreement (collectively, the "Secured Assets"). Merchant agrees to provide other security to GCF upon request to secure Merchant's obligations under this Agreement. Merchant agrees that, if at any time there are insufficient funds in Merchant's Account to cover GCF entitlements under this Agreement, GCF is granted a further security interest in all of Merchant's assets of any kind whatsoever, and such assets shall then become Secured Assets. These security interests and liens will secure all of GCF entitlements under this Agreement and any other agreements now existing or later entered into between Merchant, GCF or an affiliate of GCF. GCF is authorized to file any and all notices or filings it deems necessary or appropriate to enforce its entitlements hereunder.

This security interest may be exercised by GCF without notice or demand of any kind by making an immediate withdrawal or freezing the Secured Assets. Pursuant to Article 9 of the Uniform Commercial Code, as amended from time to time, GCF has control over and may direct the disposition of the Secured Assets, without further consent of Merchant. Merchant hereby represents and warrants that no other person or entity has a security interest in the Secured Assets. With respect to such security interests and liens, GCF will have all rights afforded under the Uniform Commercial Code, any other applicable law and in equity. Merchant will obtain from GCF written consent prior to granting a security interest of any kind in the Secured Assets to a third party. Merchant agrees that this is a contract of recoupment and GCF is not required to file a motion for relief from a bankruptcy action automatic stay to realize on any of the Secured Assets. Nevertheless, Merchant agrees not to contest or object to any motion for relief from the automatic stay filed by GCF. Merchant agrees to execute and deliver to GCF such instruments and documents GCF may reasonably request to perfect and confirm the lien, security interest and right of setoff set forth in this Agreement. GCF is authorized to execute all such instruments and documents in Merchant's name.

Additional Collateral. To secure Guarantor's performance obligations to GCF under the Guaranty, the Guarantor hereby grants GCF a security interest in **SANUWAVE SERVICES, LLC** the "Additional Collateral"). Guarantor understands that GCF will have a security interest in the aforesaid Additional Collateral upon execution of this Agreement. Merchant and Guarantor each acknowledge and agree that any security interest granted to GCF under any other agreement between Merchant or Guarantor and GCF (the "Cross-Collateral") will secure the obligations hereunder and under the Merchant Agreement.

Merchant and Guarantor each agrees to execute any documents or take any action in connection with this Agreement as GCF deems necessary to perfect or maintain GCF first priority security interest in the Collateral and the Additional Collateral, including the execution of any account control agreements. Merchant and Guarantor each hereby authorizes GCF to file any financing statements deemed necessary by GCF to perfect or maintain GCF security interest, which financing statement may contain notification that Merchant and/or Guarantor have granted a negative pledge to GCF with respect to the Collateral, and the Additional Collateral, and that any subsequent lien or may be tortuously interfering with GCF rights. Merchant and Guarantor shall be liable for, and GCF may charge and collect, all costs and expenses, including but not limited to attorney's fees, which may be incurred by GCF in protecting, preserving and enforcing GCF security interest and rights.

Negative Pledge. Merchant and Guarantor each agrees not to create, incur, assume, or permit to exist, directly or indirectly, any lien on or with respect to any of the Collateral or the Additional Collateral, as applicable.

Consent to Enter Premises and Assign lease. GCF shall have the right to cure Merchant's default in the payment of rent on the following terms. In the event Merchant is served with papers in an action against Merchant for nonpayment of rent or for summary eviction, GCF may execute its rights and remedies under the Assignment of Lease. Merchant also agrees that GCF may enter into an agreement with

Merchant's landlord giving GCF the right: (a) to enter Merchant's premises and to take possession of the fixtures and equipment therein for the purpose of protecting and preserving same; and/or (b) to assign Merchant's lease to another qualified business capable of operating a business comparable to Merchant's at such premises.

Remedies. Upon any Event of Default, GCF may pursue any remedy available at law (including those available under the provisions of the UCC), or in equity to collect, enforce, or satisfy any obligations then owing to GCF, whether by acceleration or otherwise.

GUARANTY

Personal Guaranty of Performance. The undersigned Guarantor(s) hereby guarantees to GCF, Merchant's good faith, truthfulness and performance of all of the representations, warranties, covenants made by Merchant in the Merchant Agreement in Sections thereof 2.3, 2.5, 2.6, 2.9, 2.10, 2.11, 2.12, 2.13 and 2.14, as each agreement may be renewed, amended, extended or otherwise modified (the "Guaranteed Obligations"). Guarantor's obligations are due at the time of any breach by Merchant of any representation, warranty, or covenant made by Merchant in the Agreement.

Guarantor Waivers. In the event of a breach of the above, GCF may seek recovery from Guarantors for all of GCF losses and damages by enforcement of GCF rights under this Agreement without first seeking to obtain payment from Merchant, any other guarantor, or any Collateral or Additional Collateral GCF may hold pursuant to this Agreement or any other guaranty.

GCF does not have to notify Guarantor of any of the following events and Guarantor will not be released from its obligations under this Agreement if it is not notified of: (i) Merchant's failure to pay timely any amount owed under the Merchant Agreement; (ii) any adverse change in Merchant's financial condition or business; (iii) any sale or other disposition of any collateral securing the Guaranteed Obligations or any other guaranty of the Guaranteed Obligations; (iv) GCF acceptance of this Agreement; and (v) any renewal, extension or other modification of the Merchant Agreement or Merchant's other obligations to GCF. In addition, GCF may take any of the following actions without releasing Guarantor from any of its obligations under this Agreement: (i) renew, extend or otherwise modify the Merchant Agreement or Merchant's other obligations to GCF; (ii) release Merchant from its obligations to GCF; (iii) sell, release, impair, waive or otherwise fail to realize upon any collateral securing the Guaranteed Obligations or any other guaranty of the Guaranteed Obligations ; and (iv) foreclose on any collateral securing the Guaranteed Obligations or any other guaranty of the Guaranteed Obligations in a manner that impairs or precludes the right of Guarantor to obtain reimbursement for payment under this Agreement. Until the Merchant Amount plus any accrued but unpaid interest and Merchant's other obligations to GCF under the Merchant Agreement and this Agreement are paid in full, Guarantor shall not seek reimbursement from Merchant or any other guarantor for any amounts paid by it under this Agreement. Guarantor permanently waives and shall not seek to exercise any of the following rights that it may have against Merchant, any other guarantor, or any collateral provided by Merchant or any other guarantor, for any amounts paid by it, or acts performed by it, under this Agreement: (i) subrogation; (ii) reimbursement; (iii) performance; (iv) indemnification; or (v) contribution. In the event that GCF must return any amount paid by Merchant or any other guarantor of the Guaranteed Obligations because that person has become subject to a proceeding under the United States Bankruptcy Code or any similar law, Guarantor's obligations under this Agreement shall include that amount.

Guarantor Acknowledgement. Guarantor acknowledges that: (i) He/She understands the seriousness of the provisions of this Agreement; (ii) He/She has had a full opportunity to consult with counsel of his/her choice; and (iii) He/She has consulted with counsel of its choice or has decided not to avail himself/herself of that opportunity.

Joint and Several Liability. The obligations hereunder of the persons or entities constituting Guarantor under this Agreement are joint and several.

THE TERMS, DEFINITIONS, CONDITIONS AND INFORMATION SET FORTH IN THE "MERCHANT AGREEMENT", INCLUDING THE "TERMS AND CONDITIONS", ARE HEREBY INCORPORATED IN AND MADE A PART OF THIS SECURITY AGREEMENT AND GUARANTY. CAPITALIZED TERMS NOT DEFINED IN THIS SECURITY AGREEMENT ANO GUARANTY, SHALL HAVE THE MEANING SET FORTH IN THE MERCHANT AGREEMENT, INCLUDING THE TERMS ANO CONDITIONS.

MERCHANT

BY: KEVIN A RICHARDSON II **X** Kevin A Richardson II _____ 12/22/2021
(SIGNATURE)

CEO #1: KEVIN A RICHARDSON II **X** Kevin A Richardson II _____ _____
(SIGNATURE) (DATE)

(SOCIAL SECURITY#) _____
(DRIVERS LICENSE)

CEO #2: **X** _____ _____
(SIGNATURE) (DATE)

(SOCIAL SECURITY#) _____
(DRIVERS LICENSE)

ACKNOWLEDGMENT

I, __ **KEVIN A RICHARDSON II** __ hereby acknowledge:

- **There has been no promise of additional capital in 30** days from funding by GCF Resources LLC or any ISO (broker)
    - Our policy is that merchants can seek additional capital from us when they have paid 50% of the Receipts Purchased Amount.
- There has not been and will not be any contact from third party debt companies regarding this Future Receivables Agreement dated _December 16, 2021_ .

I, the undersigned, acknowledge that I am in agreement with these items, which are also described in detail within the pages of this document.

Kevin A Richardson II	**12/22/2021**
Signature	***Date***

APPENDIX A: FEE BREAKDOWN AND SUMMARY

A. Origination Fee - $45,000.00 to cover Underwriting and related expenses.

B. ACH Program Fee - $45,000.00 (or _____% of the funded amount, depending on size of advance). ACH's are labor intensive and are not an automated process, requiring us to charge this fee to cover costs.

C. NSF Fee (Standard) - $50.00 (each) Up to THREE TIMES ONLY before a default is declared.

D. Rejected ACH - $100.00 - When Merchant directs the bank to reject our Debit ACH.

E. Bank Change Fee - $50.00 - When Merchant requires a change of Bank Account to be debited, requiring us to adjust our system.

F. Blocked Account - $5,000.00 - When Merchant BLOCKS Account from our Debit ACH which places them in default (per Contract).

G. Default Fee - $5,000.00 - When Merchant changes bank Account cutting us off from our collections.

CEO #1: KEVIN A RICHARDSON II

X. Kevin A Richardson II (SIGNATURE) 12/22/2021 (DATE)

(SOCIAL SECURITY#)

(DRIVERS LICENSE)

CEO #2:

X _____ (SIGNATURE) _____ (DATE)

(SOCIAL SECURITY#)

(DRIVERS LICENSE)

Document and Entity Information - USD ($) $ in Millions	12 Months Ended		
	Dec. 31, 2021	May 04, 2022	Jun. 30, 2021
Cover [Abstract]			
Document Type	10-K		
Amendment Flag	false		
Document Annual Report	true		
Document Period End Date	Dec. 31, 2021		
Current Fiscal Year End Date	--12-31		
Document Fiscal Year Focus	2021		
Document Fiscal Period Focus	FY		
Document Transition Report	false		
Entity File Number	000-52985		
Entity Registrant Name	SANUWAVE Health, Inc.		
Entity Central Index Key	0001417663		
Entity Incorporation, State or Country Code	NV		
Entity Tax Identification Number	20-1176000		
Entity Address, Address Line One	3360 Martin Farm Road		
Entity Address, Address Line Two	Suite 100		
Entity Address, City or Town	Suwanee		
Entity Address, State or Province	GA		
Entity Address, Postal Zip Code	30024		
City Area Code	770		
Local Phone Number	419-7525		
Entity Well-known Seasoned Issuer	No		
Entity Voluntary Filers	No		
Entity Current Reporting Status	No		
Entity Interactive Data Current	Yes		
Entity Filer Category	Non-accelerated Filer		
Entity Small Business	true		
Entity Emerging Growth Company	false		
ICFR Auditor Attestation Flag	true		
Entity Shell Company	false		
Entity Public Float			$ 81.6
Entity Common Stock, Shares Outstanding		517,195,705	
Auditor Name	Marcum LLP		
Auditor Location	New York, NY		
Auditor Firm ID	688		

CONSOLIDATED BALANCE SHEETS - USD ($) $ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Current Assets:		
Cash	$ 619	$ 2,437
Accounts receivable, net of allowance for doubtful accounts of $785 in 2021 and $343 in 2020	2,415	2,356
Inventory	1,040	2,956
Prepaid expenses and other current assets	326	179
Total Current Assets	4,400	7,928
Property and Equipment, net	668	471
Right of Use Assets, net	344	795
Other Intangible Assets, net	5,841	6,545
Goodwill	7,260	7,260
Other Assets	106	28
Total Assets	18,619	23,027
Current Liabilities:		
Senior secured promissory note payable, in default	11,586	10,676
Convertible promissory notes payable, in default	11,601	4,000
Convertible promissory notes, related parties, in default	1,596	1,596
Advances on future cash receipts	446	0
Accounts payable	7,644	4,454
Accrued expenses	4,394	2,127
Accrued employee compensation	4,247	2,541
Due under factoring agreement	1,737	0
Warrant liability	9,614	8,855
Current portion of SBA loans	158	321
Accrued interest	2,521	1,021
Accrued interest, related parties	289	77
Current portion of lease liabilities	268	451
Current portion of contract liabilities	48	32
Other	114	23
Total Current Liabilities	56,263	36,174
Non-current Liabilities		
SBA loans	875	143
Lease liabilities	118	391
Contract liabilities	293	37
Deferred tax liability	28	0
Total Non-current Liabilities	1,314	571
Total Liabilities	57,577	36,745
Commitments and Contingencies (Footnote 19)		
STOCKHOLDERS' DEFICIT		

Preferred Stock, par value $0.001, 5,000,000 shares authorized; 6,175, 293, 90 and 8 shares designated Series A, Series B, Series C and Series D, respectively; no shares issued and outstanding at December 31, 2021 and 2020	0	0
Common Stock, par value $0.001, 800,000,000 shares authorized; 481,619,621 and 470,694,621 issued and outstanding at December 31, 2021 and 2020, respectively	482	471
Additional Paid-in Capital	144,582	142,563
Accumulated Deficit	(183,949)	(156,690)
Accumulated Other Comprehensive Loss	(73)	(62)
Total Stockholders' Deficit	(38,958)	(13,718)
Total Liabilities and Stockholders' Deficit	$ 18,619	$ 23,027

CONSOLIDATED BALANCE SHEETS (Parenthetical) - USD ($) $ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Current Assets:		
Accounts receivable, allowance for doubtful accounts	$ 785	$ 343
STOCKHOLDERS' DEFICIT		
Preferred stock, par value (in dollars per share)	$ 0.001	$ 0.001
Preferred stock, shares authorized (in shares)	5,000,000	5,000,000
Preferred stock, shares issued (in shares)	0	0
Preferred stock, shares outstanding (in shares)	0	0
Common stock, par value (in dollars per share)	$ 0.001	$ 0.001
Common stock, shares authorized (in shares)	800,000,000	800,000,000
Common stock, shares issued (in shares)	481,619,621	470,694,621
Common stock, shares outstanding (in shares)	481,619,621	470,694,621
Series A Convertible Preferred Stock [Member]		
STOCKHOLDERS' DEFICIT		
Preferred stock, shares authorized (in shares)	6,175	6,175
Series B Convertible Preferred Stock [Member]		
STOCKHOLDERS' DEFICIT		
Preferred stock, shares authorized (in shares)	293	293
Series C Convertible Preferred Stock [Member]		
STOCKHOLDERS' DEFICIT		
Preferred stock, shares authorized (in shares)	90	90
Series D Preferred Conversion [Member]		
STOCKHOLDERS' DEFICIT		
Preferred stock, shares authorized (in shares)	8	8

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Revenues:		
Total Revenue	$ 13,010	$ 4,057
Cost of Revenues	4,986	1,162
Gross Margin	8,024	2,895
Operating Expenses:		
General and administrative	11,690	13,723
Selling and marketing	8,591	5,160
Research and development	1,101	1,246
Impairment of intangible assets	0	7,185
Depreciation and amortization	784	781
Total Operating Expenses	22,166	28,095
Operating Loss	(14,142)	(25,200)
Other Income (Expense):		
Interest expense	(6,883)	(2,025)
Interest expense, related party	(212)	(516)
Partnership fee income	0	600
Change in fair value of derivative liabilities	(2,622)	(3,193)
Loss on issuance of debt	(3,572)	0
Gain / (loss) on extinguishment of debt	204	(565)
Gain / (loss) on foreign currency exchange	(4)	(38)
Other Income (Expense), net	(13,089)	(5,737)
Net Loss before Income Taxes	(27,231)	(30,937)
Income tax expense	28	0
Net Loss	(27,259)	(30,937)
Other Comprehensive Loss		
Foreign currency translation adjustments	(11)	0
Total Comprehensive Loss	$ (27,270)	$ (30,937)
Loss per Share:		
Net loss per share - basic (in dollars per share)	$ (0.05)	$ (0.08)
Weighted average shares outstanding - basic (in shares)	518,355,642	378,128,645
Net loss per share - diluted (in dollars per share)	$ (0.05)	$ (0.08)
Weighted average shares outstanding - diluted (in shares)	518,355,642	378,128,645
Accessory and Parts Revenue [Member]		
Revenues:		
Total Revenue	$ 8,072	$ 1,209
Product [Member]		
Revenues:		
Total Revenue	3,116	2,267
Rental Income [Member]		

Revenues:		
Total Revenue	1,627	429
License Fees and Other [Member]		
Revenues:		
Total Revenue	$ 195	$ 152

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT - USD ($) $ in Thousands	Preferred Stock [Member]	Common Stock [Member]	Additional Paid-in Capital [Member]	Accumulated Deficit [Member]	Accumulated Other Comprehensive Loss [Member]	Total
Beginning balance at Dec. 31, 2019	$ 0	$ 294	$ 115,458	$ (125,753)	$ (62)	$ (10,063)
Beginning balance (in shares) at Dec. 31, 2019	0	293,780,400				
Increase (Decrease) in Stockholders' Equity [Roll Forward]						
Net loss	$ 0	$ 0	0	(30,937)	0	(30,937)
Proceeds from warrant exercise	$ 0	$ 1	9	0	0	10
Proceeds from warrant exercise (in shares)	0	1,000,000				
Conversion of short term notes and convertible notes payable	$ 0	$ 5	560	0	0	565
Conversion of short term notes and convertible notes payable (in shares)	0	4,829,789				
Reclassification of warrant liability to equity	$ 0	$ 0	6,293	0	0	6,293
Conversion of advances from related parties	$ 0	$ 0	18	0	0	18
Conversion of advances from related parties (in shares)	0	262,811				
Conversion of notes payable, related parties	$ 0	$ 15	2,276	0	0	2,291
Conversion of notes payable, related parties (in shares)	0	15,475,235				
Shares issued for services	$ 0	$ 13	2,533	0	0	2,546
Shares issued for services (in shares)	0	12,700,000				
Proceeds from PIPE offering, net of offering costs	$ 0	$ 125	12,558	0	0	12,683
Proceeds from PIPE offering, net of offering costs (in shares)	0	124,621,428				
Stock-based compensation	$ 0	$ 0	22	0	0	22
Proceeds from stock option exercise	$ 0	$ 0	48	0	0	48
Proceeds from stock option exercise (in shares)	0	325,000				
Beneficial conversion feature on convertible debt	$ 0	$ 0	561	0	0	561

LGH Warrant Liability	0	0	(249)	0	0	(249)
Series C and Series D preferred stock converted to common stock	$ 0	$ 18	2,432	0	0	2,450
Series C and Series D preferred stock converted to common stock (in shares)	0	17,499,958				
Inducement shares issued	$ 0	$ 0	44	0	0	44
Inducement shares issued (in shares)	0	200,000				
Foreign currency translation adjustment	$ 0	$ 0	0	0	0	0
Ending balance at Dec. 31, 2020	$ 0	$ 471	142,563	(156,690)	(62)	(13,718)
Ending balance (in shares) at Dec. 31, 2020	0	470,694,621				
Increase (Decrease) in Stockholders' Equity [Roll Forward]						
Net loss	$ 0	$ 0	0	(27,259)	0	(27,259)
Reclassification of warrant liability to equity						2,030
Foreign currency translation adjustment	0	0	0	0	(11)	(11)
Cashless warrant exercise	$ 0	$ 11	(11)	0	0	0
Cashless warrant exercise (in shares)	0	10,925,000				
Reclassification of warrant liability due to cashless warrant exercise	$ 0	$ 0	2,030	0	0	2,030
Reclassification of warrant liability due to cashless warrant exercise (in shares)	0	0				
Ending balance at Dec. 31, 2021	$ 0	$ 482	$ 144,582	$ (183,949)	$ (73)	$ (38,958)
Ending balance (in shares) at Dec. 31, 2021	0	481,619,621				

CONSOLIDATED STATEMENTS OF CASH FLOWS - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Cash Flows - Operating Activities:		
Net loss	$ (27,259)	$ (30,937)
Adjustments to reconcile net loss to net cash used by operating activities		
Amortization of intangibles	704	713
Depreciation	532	299
Bad debt expense	442	302
Impairment of intangible assets	0	7,185
Stock-based compensation	0	22
Shares issued for services	0	2,546
Shares issued for inducement	0	45
Gain/loss on extinguishment of debt	(204)	565
Income tax expense	28	0
Change in fair value of derivative liabilities	2,622	3,193
Loss on issuance of debt	3,572	0
Amortization of debt issuance costs and original issue discount	3,226	484
Accrued interest	1,506	1,098
Interest payable, related parties	212	401
Changes in operating assets and liabilities		
Accounts receivable - trade	(395)	(2,582)
Inventory	1,916	(553)
Prepaid expenses	(118)	(54)
Other assets	(111)	13
Operating leases	0	(6)
Accounts payable	3,181	3,015
Accrued expenses	1,818	1,169
Accrued employee compensation	1,837	934
Contract liabilities	82	(570)
Net Cash Used by Operating Activities	(6,409)	(12,718)
Cash Flows - Investing Activities		
Acquisition of UltraMIST, net of $4,000,000 note payable to seller	0	(20,000)
Purchases of property and equipment	(529)	(53)
Net Cash Flows Used by Investing Activities	(529)	(20,053)
Cash Flows - Financing Activities		
Proceeds from sale of convertible preferred stock	0	2,450
Proceeds from convertible promissory notes	1,928	1,100
Proceeds from SBA loan	1,033	614
Proceeds from PIPE offering, net of offering costs	0	21,456
Proceeds from senior secured promissory notes	940	13,347
Proceeds from stock option exercises	0	48
Proceeds from factoring	1,737	0

Proceeds from warrant exercises	0	10
Advances from related parties	175	23
Repayments of debt principal on convertible promissory notes, related parties, convertible promissory notes and SBA loans	(493)	(5,458)
Payments of principal on finance leases	(199)	(143)
Net Cash Flows Provided by Financing Activities	5,121	33,447
Effect of Exchange Rates on Cash	(1)	0
Net Change in Cash During Period	(1,818)	676
Cash at Beginning of Period	2,437	1,761
Cash at End of Period	619	2,437
Supplemental Information:		
Cash paid for interest	2,580	436
Non-cash Investing and Financing Activities:		
Reclassification of warrant liabilities to equity	2,030	6,293
Embedded conversion feature on convertible debt	4,138	561
Warrant issuance in conjunction with advances on future cash receipts	1,227	0
Warrant issuance in conjunction with convertible notes	1,055	0
Acquisition of UltraMIST partially financed with convertible promissory note	0	4,000
Conversion of notes payable, related parties	0	2,291
Series C and Series D preferred stock converted to common stock	0	2,450
Exchange line of credit and notes payable, related parties, for convertible promissory notes, related parties	0	1,596
Conversion of short-term notes payable to equity	0	565
Conversion of advance from related parties	$ 0	$ 18

CONSOLIDATED STATEMENTS OF CASH FLOWS (Parenthetical)	12 Months Ended Dec. 31, 2021 USD ($)
Cash Flows - Investing Activities	
Note payable to seller	$ 4,000,000

Nature of the Business and Basis of Presentation

Nature of the Business and Basis of Presentation [Abstract]

Nature of the Business and Basis of Presentation

12 Months Ended Dec. 31, 2021

1. Nature of the Business and Basis of Presentation

SANUWAVE Health, Inc. and Subsidiaries ("SANUWAVE" or the "Company") is focused on the research, development, and commercialization of its patented noninvasive and biological response activating medical systems for the repair and regeneration of skin, musculoskeletal tissue, and vascular structures. The Company's lead regenerative product in the United States is the dermaPACE® device used for treating diabetic foot ulcers.

Through the Company's acquisition, on August 6, 2020, of the UltraMIST® assets from Celularity, Inc. ("Celularity"), SANUWAVE now combines two highly complementary and market-cleared energy transfer technologies and two human tissue biologic products, which creates a platform of scale with an end-to-end product offering in the advanced wound care market.

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.

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. Accrued executive severance at December 31, 2020 of $154 thousand was reclassified from accrued expenses to accrued employee compensation. This reclassification had no effect on the previously reported operating results.

COVID-19 **–** The worldwide spread of the COVID-19 virus resulted in a global slowdown of economic activity which is likely to decrease demand for a broad variety of products, including from our customers. We have experienced a disruption of our supply channels which will continue for an unknown period of time until the global supply chain can return to the pre- disease status. Also, the pandemic may cause 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 and we expect that they will continue to have a negative impact on our sales and our results of operations, the size and duration of which we are currently unable to predict.

Going Concern	12 Months Ended Dec. 31, 2021
Going Concern [Abstract]	
Going Concern	

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 commercialization of the dermaPACE and will continue to research and develop the non-medical uses of the PACE technology, both of 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 Form 10-K.

The continuation of our business is dependent upon raising additional capital to fund operations. Management's plans are to obtain additional capital in 2022 through investments by strategic partners for market opportunities, which may include strategic partnerships or licensing arrangements, or 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 shareholders. 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. Although no assurances can be given, management believes that potential additional issuances of equity or other potential financing transactions 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.

Summary of Significant Accounting Policies	12 Months Ended Dec. 31, 2021
Summary of Significant Accounting Policies [Abstract]	
Summary of Significant Accounting Policies	

3. Summary of Significant Accounting Policies

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

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

Significant estimates include the recording of allowances for doubtful accounts, the net realizable value of inventory, useful lives of long-lived assets, fair value of goodwill and other 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.

Cash - The Company maintains its cash in bank accounts which may exceed federally insured limits.

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.

Concentration of credit risk - Management routinely assesses the financial strength of its customers and, as a consequence, 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 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.

Property and equipment **–** Property and equipment is recorded at cost, net of accumulated depreciation. The costs of additions and betterments are capitalized and expenditures for repairs and maintenance, which do not extend the economic useful life of the related assets, are expensed. The straight-line method of depreciation is used for computing depreciation on property and equipment over the following estimated useful lives:

	Estimated Useful Life
Machines and equipment	3 years
Office and computer equipment	3 years
Medical devices on rent	5 - 15 years
Software	2years
Furniture and fixtures	3 years

Goodwill and Other Intangible Assets — Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company accounts for goodwill under ASC Topic 350, *Intangibles-Goodwill and Other*. The Company tests goodwill for impairment annually, or more frequently whenever events or circumstances indicate impairment may exist. Goodwill is stated at cost less 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 for the year ended December 31, 2021. 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. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The Company has determined that there were no impairment to goodwill or intangible assets for the year ended December 31, 2021.

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. Except for the impairment of the intangible assets discussed above, the Company determined that no impairment of long-lived assets was indicated at December 31, 2021.

Leases – We determine whether an arrangement is a lease at inception. When our lease arrangements include lease and non-lease components, we account 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 sheet, and we recognize 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 our right of use assets and lease liabilities. None of our lease agreements include an option to purchase the leased asset, residual value guarantees, or material restrictive covenants.

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.

Preferred stock – The Company evaluates preferred stock issuances for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determines appropriate equity or liability accounting treatment. Additionally, the Company determines, if classified as equity, whether it would be recorded as permanent or temporary equity.

Sequencing policy – The Company follows 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 on the basis of earliest issuance date of potentially dilutive instruments with the earliest grants receiving first allocation of shares.

Convertible instruments and liabilities related to warrants issued – 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 ("ECOs") 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 as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. A binomial model was used to estimate the fair value of the ECOs of warrants 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. The expected volatility is estimated based on the actual volatility during the most recent historical period of time equal to the weighted average life of the instruments.

Warrants related to debt issued – The Company records a warrant 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 warrant discount is reported as a reduction of the related debt liability.

Beneficial conversion feature on convertible debt - The Company records a beneficial conversion feature related convertible 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 in the accompanying Consolidated Statements of Comprehensive Loss. This beneficial conversion feature is reported as a reduction of the related debt liability in the accompanying Consolidated Balance Sheet.

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

Revenue Recognition – We recognize revenue in accordance with two different Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") standards: 1) Topic 606 and 2) Topic 842.

Topic 606

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. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under previous U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In accordance with ASC 606, we apply the following the five-step model:

1. Identify the contract(s) with a customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

2. Identify the performance obligation(s) in the contract. If a contract promises to transfer more than one good or service to a customer, each good or service constitutes a separate performance obligation if the good or service is distinct or capable of being distinct.

3. Determine the transaction price. The transaction price is the amount of consideration to which we expect to be entitled in exchanging the promised goods or services to the customer.

4. Allocate the transaction price to the performance obligations in the contract. For a contract that has more than one performance obligation, we allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which we expect to be entitled in exchange for satisfying each performance obligation.

5. Recognize revenue when (or as) the Company satisfies a performance obligation. For each performance obligation, we determine whether we satisfy the performance obligation at a point in time or over time. Appropriate methods of measuring progress include output methods and input methods.

The Company recognizes revenue primarily from the following types of contracts under ASC 606:

Product Sales and Accessory and Part Sales - Product sales and 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. Device product sales are bundled with an initial one-year warranty and the Company offers a separately priced second-year warranty. The Company allocates the device sales price to the product and the embedded warranty by reference to the stand-alone extended warranty price. Because the warranty represents a stand-ready obligation, revenue is recognized over the time period 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.

Topic 842
The Company recognizes revenue primarily from the following types of contracts under ASC 842:

Rental and Pay per Use Income - Rental revenue represents revenues earned from renting equipment either on a monthly basis or on a pay per use. We account for these rental contracts as operating leases and revenue will be recognized on a straight-line basis in the period billed to the customer. However, under the pay per use agreement, the Company will earn revenues based on the number of times the device is used.

The lease terms are included in our contracts, and the determination of whether our contracts contain leases generally does not require significant assumptions or judgments. In some cases, a rental contract may contain a rental purchase option, whereby the customer has an option to purchase the rented equipment at the end of the term for a specified price. Revenues related to the rental contract will be accounted for as an operating lease as the option to purchase is not reasonably certain to be exercised. Lessees do not provide residual value guarantees on rented equipment.

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs incurred have been recorded in cost of revenues.

Research and development - Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to the Company's products in clinical development, such as payments to contract research organizations, consulting fees for FDA submissions, universities performing non-medical related research and insurance premiums for clinical studies and non-medical research. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the clinical affairs, and research and development departments are classified as research and development costs.

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 August 2020, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity,* which simplifies the accounting for convertible instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature and simplifies the guidance for determining whether a conversion feature is a derivative. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost. These changes will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that was bifurcated according to previously existing rules. In addition, ASU 2020-06 requires the application of the if-converted

method for calculating diluted earnings per share and the treasury stock method will be no longer available. The new guidance is effective for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. Effective January 1, 2021, the Company elected to early adopt ASU 2020-06 using the modified retrospective method. The adoption of ASU 2020-06 had no impact on the Company's previously reported financial position or operating results.

In June 2016, the FASB issued 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, which will result 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.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes in several areas including calculating taxes in an interim period, clarifying how to account for taxes that are partially based on income and requiring an entity to reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. This amendment is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company adopted ASU 2019-12 effective January 1, 2021 with no impact on previously reported financial position or operating results.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment. The amendments in ASU 2017-04 modified the testing that an entity should perform for its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. This amendment is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2017-04 effective January 1, 2021. The adoption of this guidance did not impact our results of operations or financial position.

In May 2021, the FASB issued Accounting Standards Update ("*ASU*") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for us on January 1, 2022. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the effect the adoption of this ASU will have on our consolidated financial statements.

Loss per Share

12 Months Ended
Dec. 31, 2021

Loss per Share [Abstract]
Loss per Share

4. 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, 2021 and 2020. 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:

	2021	2020
Weighted average shares outstanding		
Common shares	481,619,621	359,880,132
Common shares issuable assuming excercise of nominally priced warrants	36,736,021	18,248,513
Weighted average shares outstanding	518,355,642	378,128,645

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, 2021 and 2020, 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 at December 31, 2021 and 2020, respectively (dollars in thousands):

	2021	2020
Common stock options	31,760	31,938
Common stock purchase warrants	168,192	142,266
Convertible notes payable	90,380	58,657
	290,332	232,861

Asset Purchase Agreement

12 Months Ended
Dec. 31, 2021

Asset Purchase Agreement [Abstract]

Asset Purchase Agreement

5. Asset Purchase Agreement

On August 6, 2020, the Company completed an asset purchase agreement (the "Asset Purchase Agreement") with Celularity pursuant to which the Company acquired (the "Transaction") Celularity's UltraMIST® assets ("UltraMIST®", or the "Assets"). The acquisition provides the Company with a robust product offering in the advanced wound care market and gives the Company an end-to-end advanced wound care product portfolio that addresses the entire care pathway. The aggregate consideration paid for the Assets was $24.0 million, which consisted of (i) a cash payment of $18.9 million, (ii) the issuance of a convertible promissory note to Celularity in the principal amount of $4.0 million (the "Seller Note"), and (iii) a credit of $1.1 million for the previous payment made by the Company to Celularity pursuant to that certain letter of intent between the Company and Celularity dated June 7, 2020.

In connection with the Asset Purchase Agreement, on August 6, 2020, we entered into a license and marketing agreement with Celularity pursuant to which Celularity granted to the Company a license to the Celularity wound care biologic products, Biovance® and Interfyl® (the "License Agreement"). The License Agreement provides the Company with an exclusive license to use, market, distribute and sell Biovance® in the field and territory, as defined in the License Agreement, and a non-exclusive license to use, market, distribute and sell Interfyl® in the field and in the territory. The License Agreement has an initial five-year term, after which it automatically renews for additional one-year periods, unless either party provides written notice at least 180 days prior to the expiration of the current term. The license agreement calls for prepaid minimum quarterly upfront royalty of $446 thousand of payments for Biovance which are credited against sales in that quarter. At December 31, 2021 and 2020 the Company had accrued $893 thousand and $336 thousand of license fees, respectively. Royalties are based on a transfer price for each Biovance product and sales are reported on a quarterly basis to Celularity. In the event of sales in excess of the quarterly minimums, any additional royalties are due at that time.

The Company evaluated the transaction and has accounted for it as a business combination and applied the related accounting guidance as required, using the acquisition method and a fair value model.

The tables below present the consideration paid to Celularity and the fair value of the Assets acquired on August 6, 2020 (dollars in thousands):

Purchase Consideration	
Cash paid at closing	$ 18.9
Cash paid pursuant to letter of intent	1.1
Note payable to seller	4.0
Total Consideration	$ 24.0

Fair Value of Net Assets Acquired	
Inventory	$ 1.9
Property and equipment	0.4
Intangible assets (1)	14.4
Goodwill (2)	7.3
Total fair value of net assets acquired	$ 24.0

1. Intangible assets, as summarized below, are recorded at their estimated fair value. The estimated fair value of the acquired customer relationships is determined using the multi-period excess earnings method. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for

additional discussion of this impairment. The estimated fair value of the acquired patent and trade names is based on a relief from royalty method. The estimated useful lives for intangible assets were determined based on the remaining useful economic lives of the intangible assets that are expected to contribute directly or indirectly to future cash flows.

2. Goodwill represents the excess of the total purchase consideration over fair value of the assets recognized and represents the future economic benefits that we believe will result from combining the operations of SANUWAVE and UltraMIST®, including expected future synergies and operating efficiencies. Goodwill resulting from the Transaction has been assigned to the Company's lone operating segment. Goodwill is not subject to amortization and is tested for impairment annually and whenever events or changes in circumstances indicate that impairment may have occurred. The goodwill recognized is expected to be deductible for income tax purposes (dollars in thousands).

Intantible Assets	**Fair Value**	**Useful Life (Years)**
Customer relationships - UltraMIST®	$ 3.8	7
Customer relationahips - Biologics	7.6	7
Patent	2.3	19
Trade names	0.7	19
Total intangible assets	$ 14.4	

Acquisition and related costs - During the year ended December 31, 2020, acquisition costs of $1.1 million were expensed as incurred and included in general and administrative expenses in the consolidated statements of comprehensive loss. Such costs include professional fees of advisors and integration and synergy costs related to the combination of UltraMIST® and SANUWAVE.

Pro forma impact of acquisition – The table below shows summarized unaudited pro forma combined operating results of the Company for the year ended December 31, 2020 as if the UltraMIST® business acquisition had occurred on the same terms as of January 1, 2020. Pro forma adjustments have been made related to amortization of intangibles, interest expense, and income tax expense for the year ended December 31, 2020. The pro forma financial information does not reflect revenue opportunities and cost savings which the Company expected to realize as a result of the acquisition or estimates of charges related to the integration activity.

	Year Ended December 31 (unaudited)
	2020
Total revenues	$ 7.8
Net Loss	(35.6)

The unaudited pro forma combined results of operations were prepared using the acquisition method of accounting and are based on the historical financial operating results of the Company and UltraMIST®. Except to the extent realized in the year ended December 31, 2020, the unaudited pro forma information does not reflect any cost savings, operating synergies and other benefits that the Company may achieve as a result of the acquisition, or the expenses to be incurred to achieve these savings, operating synergies and other benefits. In addition, except to the extent recognized in the years ended December 31, 2020, the unaudited pro forma information does not reflect the costs to integrate the operations of UltraMIST® within the Company.

The acquired Assets were consolidated into our financial statements starting on the acquisition date. The total revenues and operating income of UltraMIST® consolidated into our financial statements since the date of acquisition through December 31, 2020 were $3.6 million and $467 thousand.

Inventory	12 Months Ended Dec. 31, 2021
Inventory [Abstract]	
Inventory	

6. Inventory

Inventory consists of the following at December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Inventory - finished goods	$ 335	$ 1,146
Inventory - parts and accessories	705	1,810
Total inventory	$ 1,040	$ 2,956

Property and Equipment

12 Months Ended
Dec. 31, 2021

Property and Equipment [Abstract]

Property and Equipment

7. Property and Equipment

Property and equipment consists of the following at December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Machines and equipment	$ 190	$ 278
Office and computer equipment	316	245
Medical devices on rent	806	513
Software	38	38
Furniture and fixtures	27	23
Other assets	102	3
Total	1,479	1,100
Accumulated depreciation	(811)	(629)
Net property and equipment	$ 668	$ 471

Depreciation expense was $182 thousand and $98 thousand for the years ended December 31, 2021 and 2020, respectively.

Goodwill and Other Intangible Assets	12 Months Ended Dec. 31, 2021
Goodwill and Other Intangible Assets [Abstract]	
Goodwill and Other Intangible Assets	

8. Goodwill and Other Intangible Assets

Changes in the carrying value of goodwill and other intangible assets during the year ended December 31, 2021 consist of the following activity:

	December 31, 2020	Amortization	Impairment	December 31, 2021	Weighted average useful life (in years)
Goodwill	$ 7,260	$ -	$ -	$ 7,260	-
Intangible assets subject to amortization					
Customer relationships - UltraMIST	$ 3,603	$ (546)	$ -	$ 3,057	2.9
Patent	2,263	(121)	-	2,142	6.4
Trade names	679	(37)	-	642	1.9
Other intangible assets	$ 6,545	$ (704)	$ -	$ 5,841	3.8

Future amortization expense is expected to be the following:

Year ending December 31,	Amortization
2022	704
2023	704
2024	704
2025	704
2026	704
Thereafter	2,321
	$ 5,841

Impairment – During the fourth quarter of 2020, the Company determined that the intangible asset for customer relationships related to the biological products was impaired due to significant shortfalls in sales of the products during that period compared with the sales projections used to determine the fair value the intangible asset as of the August 6, 2020 acquisition date. The Company does not expect sales of biological products to sufficiently recover. The estimated fair value of the customer relationships at the acquisition date and at December 31, 2020 were determined using the multi-period excess earnings method. At December 31, 2020, the Company recorded a $7.2 million impairment charge for this intangible asset in the consolidated statements of comprehensive loss.

Accrued Expenses	12 Months Ended Dec. 31, 2021
Accrued Expenses [Abstract]	
Accrued Expenses	

9. **Accrued expenses**

Accrued expenses consist of the following at December 31, 2021 and 2020:

	2021	2020
Registration penalties	$ 1,950	$ 264
License fees	893	336
Board of director's fees	507	320
Legal and professional fees	221	196
Other	823	1,011
	$ 4,394	$ 2,127

Revenue

12 Months Ended
Dec. 31, 2021

Revenue [Abstract]
Revenue

10. Revenue

Disaggregation of Revenue - The disaggregation of revenue is based on geographical region. The following table presents revenue from contracts with customers for the years ended December 31, 2021 and 2020 (dollars in thousands):

	Year ended December 31, 2021			Year ended December 31, 2020		
	United States	International	Total	United States	International	Total
Accessory and parts revenue	$ 7,770	$ 302	$ 8,072	$ 1,121	$ 88	$ 1,209
Product	2,766	350	3,116	2,179	88	2,267
License fees and other	135	60	195	-	152	152
Topic 606 Revenue	$ 10,671	$ 712	$ 11,383	$ 3,300	$ 328	$ 3,628
Rental income	1,627	-	1,627	429	-	429
Topic 842 Revenue	$ 1,627	$ -	$ 1,627	$ 429	$ -	$ 429
Total Revenue	$ 12,298	$ 712	$ 13,010	$ 3,729	$ 328	$ 4,057

Contract liabilities - As of December 31, 2021 and 2020, the Company has contract liabilities from contracts with customers as follows (dollars in thousands):

	December 31, 2021	December 31, 2020
Service agreements	$ 137	$ 69
Deposit on future equipment purchases	204	-
Total contract liabilities	341	69
Less: current portion	(48)	(32)
Non-current contract liabilities	$ 293	$ 37

During the years ended December 31, 2021 and 2020, the Company recognized revenue related to these contract liabilities of $32 thousand and $61 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 during the year ended December 31, 2021 and 2020 (dollars in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020
Beginning balance	$ 69	$ 128
New service agreement additions	100	2
Deposit on future equipment purchases	204	-
Revenue recognized	(32)	(61)
Total contract liabilities	341	69
Less current portion	(48)	(32)
Non-current contract liabilities	$ 293	$ 37

Concentration of Credit Risk and Limited Suppliers	12 Months Ended Dec. 31, 2021
Concentration of Credit Risk and Limited Suppliers [Abstract]	
Concentration of Credit Risk and Limited Suppliers	

11. 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 for the ended December 31, 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
Accounts Receivable:		
Customer A	24%	n/a
Customer B	16%	46%

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 for the years ended December 31, 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
Purchases:		
Vendor A	50%	n/a
Vendor B	21%	n/a
Vendor C	n/a	35%
Vendor D	n/a	22%
Vendor E	n/a	11%

Accounts Receivable Factoring	12 Months Ended Dec. 31, 2021
Accounts Receivable Factoring [Abstract]	
Accounts Receivable Factoring	

12. Accounts Receivable Factoring

Receivable amount transferred at 12/31/2021	2,026
Reserve amount held	(289)
Funds due to factoring at 12/31/2021	1,737

On June 17, 2021, the Company entered into a factoring agreement with Goodman Capital Finance ("Goodman"), 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 are sold with recourse back to the Company, therefore the Company accounts for the arrangement as traditional financing.

Notes Payable

12 Months Ended
Dec. 31, 2021

Notes Payable [Abstract]
Notes Payable

13. Notes payable

The following two tables summarize outstanding notes payable as of December 31, 2021 and December 31, 2020 (in thousands):

	Maturity Date	Interest Rate	Conversion Price	Principal	Remaining Debt Discount	Remaining Embedded Conversion Option	Carrying Value
Senior secured promissory note payable, in default	In default	20.25%	n/a	$ 15,000	(3,414)	-	$ 11,586
Convertible promisory notes payable, in default	In default	15.4%	$ 0.1071	6,445	(1,099)	6,255	11,601
Convertible promisory notes payable, related parties, in default	In default	14.0%	$ 0.10	1,596	-	-	1,596
SBA loan #2	February 20, 2026	1.00%	n/a	1,033	-	-	1,033
Advances on future cash receipts	March 11, 2022	n/a	n/a	1,500	(1,054)	-	446
Total debt outstanding, including amounts in default				25,574	(5,567)	6,255	26,262
Less: current maturities, including notes in default				(24,699)	5,567	(6,255)	(25,387)
Total long-term debt as of December 31, 2021				$ 875	$ -	$ -	$ 875

	Maturity Date	Stated Interest Rate	Conversion Price	Principal	Remaining Debt Discount	Carrying Value
Senior secured promissory note payable, in default	In default	20.25%	n/a	$ 15,000	(4,324)	$ 10,676
Convertible promissory notes payable, in default:						
Seller Note	In default	17.00%	$ 0.10	4,000	-	4,000
Convertible promissory notes payable, related parties, in default:						
Convertible promissory notes (HealthTronics), related parties	In default	14.0%	$ 0.10	1,596	-	1,596
SBA loan #1	May 28, 2022	1.00%	n/a	464	-	464
Total debt outstanding, including amounts in default				21,060	(4,324)	16,736
Less: current maturities, including notes in default				(20,917)	4,324	(16,593)
Total long-term debt as of December 31, 2020				$ 143	$ -	$ 143

Senior secured promissory note payable, in default ("Senior Secured Note") - On August 6, 2020, the Company entered into a Note and Warrant Purchase and Security Agreement (the "NWPSA"), with NH Expansion Credit Fund Holdings LP, as noteholder and agent. 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 (the "NH Expansion Warrant") in exchange for cash to support operations, repay outstanding debt and close on the acquisition of the UltraMIST® assets from Celularity, among other transactions. As of December 31, 2020, the Company was in default of the minimum liquidity provisions on the Senior Secured Note. As of December 31, 2021, the Company remains in default of the minimum liquidity provisions on the Senior Secured Note, and, as a result, it is classified in current liabilities in the accompanying consolidated balance sheets. As a result of the default, the Company is accruing interest at the default interest note 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 for the twelve months ended December 31, 2021 was $910 thousand and is included in interest expense. Accrued interest related to the Senior Secured Note was $1.6 million and $642 thousand at December 31, 2021 and December 31, 2020, respectively. Interest expense on the Senior Secured Note was $3.1 million and $1.5 million for the years ended December 31, 2021 and 2020, respectively.

Convertible promissory notes payable, in default ("Seller Note") - On August 6, 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, 2021 and December 31, 2020, the Seller Notes had outstanding accrued interest of $761 thousand and $192 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.

April 2021 Securities Purchase Agreement and Warrants (In default) - On April 20, 2021, the Company entered into a Securities Purchase Agreement (the "Leviston Purchase Agreement"), with Leviston Resources, LLC, an accredited investor ("Leviston") for the sale by the Company in a private placement (the "Private Placement") of (i) the Company's future advance convertible promissory note in an aggregate principal amount of up to $3.4 million (the "Leviston Note") and (ii) a warrant to purchase an additional 16,666,667 shares of common stock of the Company (the "Leviston Warrant"). The Leviston Warrant has an exercise price of $0.18 per share and a four-year term. The closing of the Private Placement occurred on April 20, 2021 (the "Leviston Closing Date").

As noted above, on April 20, 2021, the Company issued the Leviston Note to the Purchaser in an aggregate principal amount of up to $3.4 million (the "Aggregate Amount"), which shall be advanced in disbursements by the Purchaser ("Leviston Disbursements"), as set forth in the Leviston Note. On May 14, 2021, the Leviston Note was amended to increase the Aggregate Amount to $4.2 million. On April 21, 2021, the Purchaser advanced a Leviston Disbursement of $750 thousand, which is net of an original issue discount of 8%. On May 14, 2021, the Purchaser advanced a second Leviston Disbursement of $750 thousand, also net of an original issue discount of 8%. A $250 thousand Leviston Disbursement was made on September 3, 2021, which was subject to the same terms and conditions of the April and May Leviston Disbursements. In addition, a $500 thousand disbursement was made on September 3, 2021 in accordance with notes issued to five institutional investors (the "Five Institutions' Notes"), which were subject to substantially the same terms and conditions as the Leviston Disbursements. Accrued interest related to the Securities Purchase Agreement and Warrants was $169 thousand at December 31, 2021. Interest expense on the Securities Purchase Agreement and Warrants was $169 thousand for the year ended December 31, 2021.

December 2021 Advance on Future Receipts Financing - On December 22, 2021, the Company paid off the remaining balance of $650 thousand from the September 27, 2021 advance and received $758 thousand in cash proceeds related to its entry into a non-recourse agreement for the sale of $1.5 million of future receipts to GCF. In conjunction with the 24-week agreement, the Company is obligated to remit to GCF a minimum of $59 thousand of receipts each week for the first six weeks and receipts of $98 thousand for the remaining 18 weeks. After considering the payments made at closing, the Company will record an initial liability of $1.5 million and a debt discount of approximately $90 thousand, which represents the original issue discount and the fees paid in conjunction with the financing. The debt discount will be amortized to interest expense over the life of the agreement. The Company will begin making the required minimum weekly payments January 3, 2022 and is obligated to continue through June 13, 2022. At closing, the Company also issued warrants to purchase 8,333,334 shares of the Company's common stock to affiliates of GCF. The warrants have an exercise price of $0.18 per share and expire four years after issuance. The Company has evaluated the terms of the warrants and after review has determined that these warrants meet the definition of a derivative liability and accordingly, were recorded as additional discount against the debt at issuance.

Warrant issuances to Leviston and Five Institutions' in April, May and September 2021

On April 20, 2021, May 14, 2021 and September 3, 2021, respectively, Leviston was issued 3,968,254, 3,968,254 and 1,322,751, warrants for shares of common stock. On September 3, 2021, the Company also issued a total of 2,777,779 warrants for shares of common stock to Five Institutions. After evaluating the terms of the warrants the Company determined that these warrants meet the definition of a derivative liability and accordingly, were recorded as additional discount against the debt at issuance. See details of the associated warrant issuances at Note 15 – Warrant Liabilities.

Embedded Conversion Option Liability

The disbursements made in April, May and September 2021 under the Leviston Notes and the Five Institutions' Notes included a Conversion Option that meets the definition of a derivative liability and, accordingly, is required to be bifurcated. The fair value of Conversion Option liability was determined by using a binomial pricing model (dollars in thousands):

Valuation at December 31, 2021	Principal	Conversion Price[(1)]	Interest Rate (annual) [(2)]	Volatility (annual) [(3)]	Time to Maturity (Years)	Fair Value of Conversion Option
Leviston Issuances	$ 1,902	0.109	0.16%	303.20%	0.4	$ 5,204
Five Institution Issuances	544	0.109	0.26%	249.00%	0.7	1,051
	$ 2,446					$ 6,255

(1) Based on the terms provided in the warrant agreement to purchase common stock of the Company as of December 31, 2021.
(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.

Valuation at issue dates	Principal	Conversion Price[(1)]	Interest Rate (annual) [(2)]	Volatility (annual) [(3)]	Time to Maturity (Years)	Fair Value of Conversion Option
Leviston Issuances	$ 1,902	0.18	0.07%	73.10%	1.0	$ 3,206

Five Institution Issuances	544	0.18	0.08%	80.10%	1.0	932
	$ 2,446					$ 4,138

(1) Based on the terms provided in the warrant agreement to purchase common stock of the Company on the stated issuance dates.
(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.

Interest rates on Leviston and Five Institutions' Notes, Conversion Option, and Loss on Issuance
The Leviston Disbursements and Five Institutions' Disbursements in April, May and September 2021, bear interest at the rate of 5% per annum and the default rate of 15%. The Leviston Note and Five Institutions' Notes contains a conversion option ("Conversion Option") and because they are in default, the Leviston and Five Institutions' Notes are convertible into common shares of the Company at a conversion price of 75% of the lowest VWAP during the ten trading days ending on the conversion date. For the Five Institutions' Note this conversion rate shall be no lower than $0.01. The Conversion Option within the Leviston and Five Institutions' Notes are required to be bifurcated at fair value, which was approximately $1.4 million on the April disbursement and $1.4 million on the May disbursement and $1.4 million on the September disbursements, which resulted in additional debt discounts being recorded at each disbursement date. Because the combined fair value of the applicable warrants and conversion option exceeded the face value of the note, the additional amount beyond the face value is recorded as a loss on issuance of $1.4 million on the April disbursement and $1.1 million on the May disbursement and $1.1 million on the September disbursement. The remaining disbursements up to the Aggregate Amount are subject to the satisfaction of certain terms and conditions set forth in the applicable notes. The disbursements bear an interest at a rate of five percent (5%) per annum and have a maturity date of twelve (12) months from the date of issuance. The Leviston and Five Institutions' Notes are convertible at the option of the holder into shares of the common stock of the Company at a conversion price per share equal to the lesser of (i) $0.18, and (ii) ninety percent (90%) of the closing price for a share of common stock reported on the OTCQB on the effective date of the Registration Statement (as defined below).

The Leviston and Five Institutions' Note contains customary events of default and covenants, including limitations on incurrences of indebtedness and liens.

Pursuant to the Leviston Purchase Agreement and purchase agreements with the Five Institutions (the "Five Institutions' Purchase Agreements"), the Company has agreed, within a reasonable period of time following the applicable closing date, and in any event prior to any Leviston Disbursement under the Leviston Note subsequent to the initial Leviston Disbursement, to enter into a security agreement in favor of the Leviston or the Five Institutions, as applicable, securing the Company's obligations under the applicable notes.

The rights of Leviston and the Five Institutions to receive payments under the applicable notes are subordinate to the rights of North Haven Expansion pursuant to the subordination agreements that the Company and Leviston, and the Company and the Five Institutions entered into with North Haven Expansion on April 20, 2021 and September 3, 2021, respectively, in connection with the Private Placement (the "Subordination Agreement").

In connection with the Leviston Purchase Agreement, the Company entered into a registration rights agreement with the Leviston on April 20, 2021 (the "Leviston Registration Rights Agreement") pursuant to which the Company agreed to file a registration statement (the "Registration Statement") with the SEC no later than thirty days following the Leviston Closing Date for the registration of 100% of the maximum number of the shares issuable upon conversion of the Leviston Note and exercise of the Leviston Warrants issued pursuant to the Leviston Purchase Agreement (the "Leviston Registrable Securities"). The Company shall use its best efforts to keep the Registration Statement continuously effective under the Securities Act of 1933, as amended (the "Securities Act"), until all Leviston Registrable Securities have been sold, or may be sold without the requirement to be in compliance with Rule 144(c)(1) of the Securities Act and otherwise without restriction or limitation pursuant to Rule 144 of the Securities Act, as determined by the counsel to the Company. The Company has yet to file the Registration Statement and, under the terms of the Leviston Registration Rights Agreement, it is obligated to pay in cash a one-time aggregate amount of $250 thousand to the holders of the Leviston Notes, plus 1% of the outstanding principal for each 30-day period during which the Company continues not to have in-place an effective Registration Statement.

On August 31, 2021, Leviston notified the Company that it was in default of the Leviston Purchase Agreement effective June 11, 2021, for failure to timely file a Registration Statement. From the date of the default, interest on the amounts due to Leviston is calculated at the default interest rate of 15% in addition to the registration penalties stated above.

The Company also entered into registration rights agreements with each of the Five Institutions on September 3, 2021. The terms and conditions of the Five Institutions' registration rights agreements are substantially similar to the Leviston Registration Rights Agreement, with two exceptions: (1) the Five Institutions may be entitled to a pro-rata share of the $250 thousand one-time aggregate amount (approximately $56 thousand) and (2) the 1% of outstanding principal payment amount for each 30-day period is capped at 5% of outstanding principal.

Convertible promissory notes payable (HealthTronics), in default - On August 6, 2020, the Company issued to HealthTronics, Inc. a convertible note payable in the amount of $1.4 million (the "HealthTronics Note"). The HealthTronics 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 HealthTronics Note and, accordingly, it began accruing additional interest of 2.0% in addition to the 12.0% stated interest rate, as of the date of the default. The convertible promissory note is expressly subordinate to the Senior Secured Notes. The Company may prepay the outstanding principal balance, together with any accrued but unpaid interest without premium or penalty. On December 31, 2021 and December 31, 2020, accrued interest of $241 thousand and $66 thousand, respectively, remained outstanding on the HealthTronics Note.

As the Seller Note was not repaid prior to January 1, 2021, HealthTronics may elect to convert the outstanding principal amount plus any accrued but unpaid interest thereon into shares of the Company's common stock, at a conversion price of $0.10 per share. 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 (Stolarski), in default - On August 6, 2020, the Company issued to A. Michael Stolarski, a member of the board of directors and an existing shareholder, a convertible promissory note in the principal amount of $223 thousand (the "Stolarski Note"). The Stolarski 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 Stolarski Note and, accordingly, it began accruing additional interest of 2.0% in addition to the 12.0% initial rate, as of the date of the default. On December 31, 2021 and December 31, 2020 accrued interest of $41 thousand and $11 thousand, respectively, remained outstanding on the Stolarski Note. The Stolarski Note is expressly subordinate to the Senior Secured Notes. The Company may prepay the outstanding principal balance, together with any accrued but unpaid interest without premium or penalty.

As the Stolarski Note was not repaid prior to January 1, 2021, the holder may elect to convert the outstanding principal amount plus any accrued but unpaid interest thereon into shares of common stock at a conversion price of $0.10 per share. 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.

September 2021 Advances on Future Receipts Financing – On September 27, 2021, the Company received $703 thousand in cash proceeds related to its entry into a non-recourse agreement for the sale of $1.0 million of future receipts to GCF Resources LLC ("GCF"). In conjunction with the 24-week agreement, the Company is obligated to remit to GCF a minimum of $59 thousand of receipts each week, with the sum of the first four payments occurring at closing, which was September 27, 2021. After taking into account the payments made at closing, the Company recorded an initial liability of $763 thousand and a debt discount of approximately $60 thousand, which represents the original issue discount and the fees paid in conjunction with the financing. The debt discount will be amortized to interest expense over the life of the agreement. The Company began making the required minimum weekly payments October 25, 2021. At closing, the Company also issued warrants to purchase 5,555,556 shares of the Company's common stock to affiliates of GCF. The warrants have an exercise price of $0.18 per share and expire four years after issuance. The Company determined that these warrants meet the definition of a derivative liability and accordingly, were recorded as additional discount against the debt at issuance.

SBA Loan #1 - The Company received a letter from the Small Business Administration ("SBA") dated August 27, 2021 forgiving approximately $454 thousand of the SBA Loan #1 principal and $6 thousand of interest, which resulted in the Company recognizing a gain on extinguishment of debt of $460 thousand during the third quarter of 2021.

SBA Loan #2 – On February 20, 2021, the Company received proceeds from a second SBA loan ("SBA Loan #2") in the amount of $1.03 million from Northeast Bank, as lender, pursuant to the Paycheck Protection Program ("PPP") under the CARES Act. SBA Loan #2 is evidenced by a promissory note that matures on February 20, 2026 and bears interest of 1% per annum. Equal monthly payments of principal and interest commence in June 2022, after both a 24-week "covered period" and a 10-month "deferment period," as defined in the promissory note and current SBA regulations. The SBA Loan #2 contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties and covenants. The SBA Loan #2 may be prepaid by the Company at any time prior to maturity with no penalties.

All or a portion of SBA Loan #2 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 ultimate forgiveness of SBA Loan #2 is also contingent upon regulatory authorities concurring with management's good faith assessment that the current economic uncertainty made the loan request necessary to support ongoing operations. If, despite the Company's good-faith belief that given the circumstances the Company satisfied all eligibility requirements for SBA Loan #2, the Company is later determined to have violated any applicable laws or regulations or it is otherwise determined that the Company was ineligible to receive SBA Loan #2, the Company may be required to repay SBA Loan #2 in its entirety and/or be subject to additional penalties. In the event SBA Loan #2, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal. As of December 31, 2021, $158 thousand is included in current liabilities and the remainder of the $875 thousand loan balance is included in non-current liabilities in the accompanying consolidated balance sheets.

Common Stock Purchase Warrants	12 Months Ended Dec. 31, 2021
Common Stock Purchase Warrants [Abstract]	
Common Stock Purchase Warrants	

14. Common Stock Purchase Warrants

A summary of the warrant activity during the years December 31, 2021 and 2020 is as follows:

	Warrants	Weighted Average Exercise Price per share	Weighted Average Remaining Contractual Life (years)
Warrants at December 31, 2019	9,474,091	$ 0.11	5.03
Issuances	189,182,645	0.19	
Exercised	(8,200,000)	0.10	
Forfeited or expired	(100,000)	0.20	
Outstanding at December 31, 2020	190,356,736	$ 0.19	3.43
Issuances	25,925,928	0.18	
Exercised	(11,400,000)	0.01	
Forfeited or expired	-	-	
Outstanding at December 31, 2021	204,882,664	$ 0.20	2.54

On February 3, 2021, the Company issued 10,925,000 shares of its commons stock to LGH upon the cashless exercise of 11,400,000 of the LGH Warrants under the terms of the warrant agreement. After this cashless exercise, 23,600,000 of LGH Warrants remain outstanding.

Fair Value Measurements

12 Months Ended
Dec. 31, 2021

Fair Value Measurements [Abstract]

Fair Value Measurements

15. Fair Value Measurements

In accordance with ASC 820 (Fair Value Measurements and Disclosures), the Company uses various inputs to measure the outstanding warrants and certain embedded conversion features associated with a convertible debt on a recurring basis to determine the fair value of the liability.

The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy as of December 31, 2021 and 2020 (in thousands):

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

	Fair value measured at December 31, 2020			
	Fair value at December 31, 2020	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 8,855	-	-	8,855
Embedded conversion option	-	-	-	-
Total fair value	8,855	-	-	8,855

There were no transfers between Level 1, 2 or three during the years ended December 31, 2021 and 2020.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2021 and 2020. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g. changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs (in thousands):

	Warrant Liability	Embedded Conversion Feature	Total
Balance December 31, 2019	$ -	$ -	$ -
Warrants classified as liabilities	11,955	-	11,955
Warrants reclassified as equity	(6,293)	-	(6,293)
Change in fair value	3,193	-	3,193
Balance December 31, 2020	$ 8,855	$ -	$ 8,855
Cashless exercise	(2,030)	-	(2,030)
Warrants classified as liabilities	2,282	-	2,282
Transfer to convertible feature	-	4,139	4,139
Change in fair value	507	2,116	2,623
Balance December, 2021	$ 9,614	$ 6,255	$ 15,869

A summary of the warrant liability activity for the year ended December 31, 2021 is as follows:

	Warrants Outstanding	Fair Value per Share	Fair Value
Balance December 31, 2019	-	$ -	$ -
Warrants classified as liabilities	112,210,902	0.11	11,955,454

Warrants reclassified as Equity	(64,119,742)	0.10	(6,292,695)
Gain on remeasurement of warrant liability	-		3,192,620
Balance December 31, 2020	48,091,160	$ 0.18	$ 8,855,379
Cashless exercise of LGH Warrants	(11,400,000)	0.18	(2,030,052)
Warrants classified as liabilities	25,926,028	0.10	2,282,262
Gain on remeasurement of warrant liability	-		506,545
Balance December, 2021	62,617,188	$ 0.15	$ 9,614,134

Significant Black Scholes valuation model inputs related to the Company's different Warrants at December 31, 2021 and 2020 are listed below.

	2021	2020
Weighted average expected life in years	4.67	7.00
Weighted average volatility	116%	121%
Weighted average risk free interest rate	1.2%	0.5%
Expected dividend yield	0.00%	0.00%

Leases

12 Months Ended
Dec. 31, 2021

Leases [Abstract]

Leases

16. Leases

The following is a summary of the Company's right of use assets and lease liabilities at December, 2021 and 2020 (in thousands):

	December 31, 2021			December 31, 2020		
	Operating Leases	Financing Leases	Total	Operating Leases	Financing Leases	Total
Right of use assets	$ 725	$ 626	$ 1,351	$ 725	$ 644	$1,369
Less: Accumulated amortization	(574)	(433)	(1,007)	(339)	(235)	(574)
Right of use assets, net	$ 151	$ 193	$ 344	$ 386	$ 409	$ 795
Lease liabilities	$ 157	$ 229	$ 386	$ 415	$ 427	$ 842
Less: current portion	(83)	(185)	(268)	(257)	(194)	(451)
Lease Liabilities	$ 74	$ 44	$ 118	$ 158	$ 233	$ 391

Total lease costs for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	2021	2020
Finance lease costs:		
Amortization of right-of-use assets	$ 217	$ 94
Interest on lease liabilities	41	33
Operating lease costs	350	118
Total lease costs	$ 608	$ 245

The following summarizes cash paid for amounts included in the measurement of lease liabilities as well as the related right-of-use assets obtained for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from finance leases	$ (234)	$ (103)
Operating cash flows from operating leases	$ (350)	$ (118)

Operating Leases - As of December 31, 2021, the maturities of the Company's operating lease liability, which have initial or remaining lease terms in excess of one year, consist of the following (in thousands):

	Amount
Year ending December 31,	
2022	$ 96
2023	68
2024	11
Total lease payments	175
Less: Present value adjustment	(18)
Lease liability	$ 157

As of December 31, 2021, the Company's operating leases had a weighted average remaining lease term of 1.1 years and a weighted average discount rate of 12.0%.

Rent expense for the years ended December 31, 2021 and 2020 was $362 thousand and $297 thousand, respectively.

Financing Lease - As of December 31, 2021, the maturities of the Company's financing lease liability, which have initial or remaining lease terms in excess of one year, consist of the following (in thousands):

	Amount
Year ending December 31,	
2022	$ 200
2023	18
Total lease payments	218
Present value adjustment	11
Lease liability	$ 229

As of December 31, 2021, the Company's financing leases had a weighted average remaining lease term of 1.0 years based on annualized base payments expiring through 2023 and a weighted average discount rate of 13.2%.

As of December 31, 2021, the Company did not have additional operating or financing leases that have yet commenced.

Common Stock	12 Months Ended Dec. 31, 2021
Common Stock [Abstract]	
Common Stock	

17. Common Stock

On July 23, 2020, in connection with the Company's 2020 Annual Meeting of Stockholders, the Company's stockholders approved, among other matters, an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 355,000,000 to 600,000,000.

Also on July 23, 2020, the Company's stockholders approved the Company to amend the Company's Articles of Incorporation to effect a reverse split of the Company's outstanding common stock at a ratio of between 1-for-10 and 1-for-50, with the exact ratio to be determined by the board of directors of the Company in its sole discretion. The Company has not yet effected a reverse split of its stock.

On December 30, 2020, the Company held a special meeting of stockholders (the "Special Meeting"). At the Special Meeting, the Company's stockholders approved an amendment to the Company's Articles of Incorporation, as amended, to increase the number of authorized shares of its common stock, par value $0.001 per share, to 800,000,000, and the Company filed a Certificate of Amendment to its Articles of Incorporation, as amended with the Secretary of State of the State of Nevada on December 30, 2020 to reflect this amendment, which became effective on December 30, 2020.

Preferred Stock	12 Months Ended Dec. 31, 2021
Preferred Stock [Abstract]	
Preferred Stock	

18. Preferred Stock

On January 31, 2020, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series C Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate 90 shares of our preferred stock as Series C Convertible Preferred Stock.

On February 6, 2020, the Company entered into a Series C Preferred Stock Purchase Agreement (the "Series C Purchase Agreement") with certain accredited investors for the sale by the Company in a private placement of an aggregate of 90 shares of the Company's Series C Convertible Preferred Stock, par value $0.001 per share at a stated value equal to $25 thousand per share, for an aggregate total purchase price of $2.3 million.

On May 14, 2020, the Company filed a Certificate of Designation of Preferences, Right and Limitations of Series D Convertible Preferred Stock of the Company with the Nevada Secretary of State which amended our Articles of Incorporation to designate eight shares of our preferred stock as Series D Convertible Preferred Stock.

On May 14, 2020, the Company entered into a Series D Preferred Stock Purchase Agreement (the "Series D Purchase Agreement") with certain accredited investors for the sale by the Company in a private placement of an aggregate of eight shares of the Company's Series D Convertible Preferred Stock, par value $0.001 per share at a stated value equal to $25 thousand per share (the "Series D Preferred Stock"), for an aggregate total purchase price of $200 thousand.

Subject to the terms of the Certificates of Designation, each share of Series C Preferred Stock and Series D Preferred Stock is convertible into shares of common stock of the Company at a rate equal to the stated value of such share of Series C Preferred Stock and Series D Preferred Stock of $25 thousand, divided by the conversion price of $0.14 per share (subject to adjustment from time to time upon the occurrence of certain events as described in the Certificate of Designation). The Certificates of Designation became effective upon filing with the Secretary of State of the State of Nevada. If all outstanding shares of Series C Preferred Stock and Series D Preferred Stock were converted into common stock at the original conversion rate, such shares would convert into an aggregate of 17,500,000 shares of common stock.

On September 20, 2020, the Series C and D holders converted their preferred shares into 17,499,958 shares of common stock.

Commitments and Contingencies	12 Months Ended Dec. 31, 2021
Commitments and Contingencies [Abstract]	
Commitments and Contingencies	

19. Commitments and Contingencies

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

Supplier disputes - In May 2021, the Company received notification alleging that it is not in compliance with the license agreement with Celularity entered into in connection with the acquisition of the UltraMIST® assets. The Company has 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.

Related party transactions	12 Months Ended Dec. 31, 2021
Related Party Transactions [Abstract]	
Related Party Transactions	

20. Related party transactions

February 2018 dermaPACE® Purchase - On February 13, 2018, the Company entered into an Agreement for Purchase and Sale, Limited Exclusive Distribution and Royalties, and Servicing and Repairs with Premier Shockwave Wound Care, Inc., a Georgia Corporation ("PSWC"), and Premier Shockwave, Inc., a Georgia Corporation ("PS"). Each of PS and PSWC is owned by A. Michael Stolarski, a member of the Company's board of directors and a shareholder of the Company. The agreement provides for the purchase by PSWC and PS of dermaPACE® System and related equipment sold by the Company along with limited but exclusive distribution rights to provide dermaPACE® Systems to certain governmental healthcare facilities in exchange for the payment of certain royalties to the Company. The agreement also 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. The purchase price for this agreement is 5.5 times the annualized EBITDA for the six months trailing the change of control plus the book value of the equipment and working capital.

During the years ended December 31, 2021 and 2020, respectively, the Company recorded $32 thousand and $45 thousand in revenue from this entity. In addition, contract liabilities include a balance of $38 thousand at December 31, 2021 and $70 thousand at December 31, 2020 from this related party.

March 2021 Future Purchase of Equipment - In March 2021, PSWC paid the Company $125 thousand as a deposit for future purchase of new medical equipment.

July 2021 dermaPACE® Purchase - On July 1, 2021, the Company purchased unused DermaPace 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.

July 2021 Rental Equipment Agreement - Also, effective July 1, 2021, the Company entered into a short-term equipment rental agreement with PSWC, whereby the Company obtained DermaPace equipment from PSWC for $3,600 per month.

October 2021 Advance from Director – On October 27, 2021 the Company received $25 thousand from A. Michael Stolarski (the "Stolarski Advance"). In exchange for the Stolarski Advance, as well as the $125 thousand deposit received in March 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.

April 2022 Advance from Director - On April 1, 2022 the Company entered into an Advance 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 ("Stolarski Advance").

The Stolarski Advance has 18 UltraMIST® systems used as collateral (the "Collateral") and the Company has agreed to repurchase the Collateral at $256 thousand.

Stock-based Compensation

12 Months Ended
Dec. 31, 2021

Stock-based Compensation [Abstract]

Stock-based Compensation

21. 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 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 particular form and conditions of each option. The stock options granted under the Stock Incentive Plan are 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, 2021 and 2020, the Stock Incentive Plan reserved a total of 35,000,000 and 35,000,000, respectively, shares of common stock for grant.

The following is a summary of the activity of the Stock Incentive Plan for the years ended December 31, 2021 and 2020:

	Options	Weighted Average Exercise Price per share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	34,303,385	$ 0.28	6.62	$ 981,088
Granted	100,000	0.26		
Exercised	(325,000)	0.15		
Forfeited or expired	(2,140,000)	0.71		
Outstanding at December 31, 2020	31,938,385	0.26	5.94	$ 1,372,116
Granted	-	-		
Exercised	-	-		
Forfeited or expired	(179,000)	0.18		
Outstanding at December 31, 2021	31,759,385	0.26	4.92	$ 1,056,236
Vested and exercisable at December 31, 2021	31,409,385	$ 0.26	4.92	$ 1,056,236

On December 31, 2021, there were 3,240,615 shares of common stock available for grant under the Stock Incentive Plan.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the year ended December 31, 2020 is shown below:

	2020
Weighted average expected life in years	5.00
Weighted average volatility	124%
Weighted average risk free interest rate	1.6%
Expected dividend yield	0.00%

For the years ended December 31, 2021 and 2020, the Company recognized $0 thousand and $22 thousand, respectively, as compensation cost related to options granted. The compensation cost is included in operating expenses in the accompanying consolidated statements of comprehensive loss. As of December 31, 2021 and 2020, there are no unamortized compensation costs related to options granted.

Joint ventures	12 Months Ended Dec. 31, 2021
Joint ventures [Abstract]	
Joint ventures	

22. Joint ventures

On December 13, 2019, the Company entered into a joint venture agreement (the "Agreement") with Universus Global Advisors LLC, a limited liability company organized under the laws of the State of Delaware ("Universus"), Versani Health Consulting Consultoria em Gestão de Negócios EIRELI, an empresa individual de responsabilidade limitada organized under the laws of Brazil ("Versani"), Curacus Limited, a private limited company organized under the laws of England and Wales ("Curacus"), and certain individual citizens of Brazil and the Czech Republic (the individuals together with Curacus, the "IDIC Group"). The principal purpose of the joint venture company will be to manufacture, import, use, sell, and distribute, on an exclusive basis in Brazil, dermaPACE devices and wound kits consisting of a standard ultrasound gel and custom size sterile sleeves used for the treatment of various acute and chronic wounds using extracorporeal shockwave therapy technology. The joint venture company will also provide treatments related to the dermaPACE devices. The IDIC Group has agreed to pay to the Company a partnership fee in the total amount of $600,000 for the granting of exclusive territorial rights to the joint venture company to distribute the dermaPACE devices and wound kits in Brazil. The $600,000 partnership fee was received and recognized as nonoperating income during the year ended December 31, 2020. The IDIC Group will also have the right to receive prioritized dividends until full reimbursement of the partnership fee and expenses incurred in the formation of the joint venture company, which are required to be paid by the IDIC Group.

Income taxes

Income taxes [Abstract]

Income taxes

12 Months Ended
Dec. 31, 2021

23. 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 for the years ended December 31, 2021 and 2020 are as follows (dollars in thousands):

	2021	2020
Domestic	$ (27,208)	$ (30,945)
Foreign	(23)	8
Net loss before income taxes	$ (27,231)	$ (30,937)

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 of a deferred tax asset will not be realized.

On March 27, 2020, the CARES Act was enacted in response to COVID-19 pandemic. Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. The CARES Act made various tax law changes including among other things (i) increasing the limitation under Section 163(j) of the Internal Revenue Code of 1986, as amended (the "IRC") for 2019 and 2020 to permit additional expensing of interest (ii) enacting a technical correction so that qualified improvement property can be immediately expensed under IRC Section 168(k), (iii) making modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes and (iv) enhancing the recoverability of alternative minimum tax credits. The CARES Act did not have a material impact on the Company.

The income tax provision (benefit) from continuing operations consists of the following at December 31, 2021 and 2020 (dollars in thousands):

Current:	2021	2020
Federal	$ -	$ -
State	28	-
Foreign	-	-
	28	-
Deferred:		
Federal	(5,038)	(5,420)
State	(869)	(964)
Foreign	4	1
Change in valuation allowance	5,903	6,383
	$ 28	$ -

At December 31, 2021 and 2020, 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, 2021 and 2020 to pretax loss from operations as a result of the following for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Tax expense (benefit) at statutory rate	$ (5,718)	$ (6,498)
Increase (reduction) in income taxes resulting from:		
State income taxes (benefits), net of federal benefit	(837)	(913)
Non-deductible gain on warrant adjustment valuation	417	670
Income from foreign subsidiaries	-	2
Change in valuation allowance	5,903	6,383
Registration penalties	354	-
Other	(91)	356
Income tax expense (benefit)	$ 28	$ -

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2021 and 2020 are as follows (dollars in thousands):

	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 33,238	$ 28,048
Net operating loss carryforwards - foreign	23	19
Excess of tax basis over book value of property and equipment	14	8
Excess of tax basis over book value of intangible assets	1,632	1,811
Stock-based compensation	1,613	1,613
Accrued employee compensation	698	427
Capitalized equity costs	49	49
Net change in reserve accounts	898	287
	38,165	32,262
Valuation allowance	(38,165)	(32,262)
Net deferred tax asset	$ -	$ -

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, 2021 and 2020.

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 and state net operating loss carryforwards of approximately $77.9 million from years ending December 31, 2005 through December 31, 2017 will begin to expire in 2025. The federal and state net operating loss carryforward for the years ended December 31, 2018 through 2021 of approximately $56.5 million will not expire. The foreign net operating loss carryforward at December 31, 2019 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 in the course of 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, 2021 and 2020. 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, 2021 and 2020, the Company did not have any amounts recorded for interest and penalties.

Subsequent Events	12 Months Ended Dec. 31, 2021
Subsequent Events [Abstract]	
Subsequent Events	**24. Subsequent events**

Warrant Exercises **–** The Company received $0.1 million in proceeds related to the exercise of 15.9 million warrants (cash and cashless) and issued 14.9 million shares.

Second Amendment to Note and Warrant Purchase and Security Agreement - The Company received $3.0 million in proceeds related to the issuance of a $3.0 million dollar note, 20.7 million Advisor shares, and 15.5 million warrants with an exercise price of $0.18 and a 10 year term.

Summary of Significant Accounting Policies (Policies)	12 Months Ended Dec. 31, 2021

Summary of Significant Accounting Policies [Abstract]

Estimates

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, useful lives of long-lived assets, fair value of goodwill and other 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.

Cash

Cash - The Company maintains its cash in bank accounts which may exceed federally insured limits.

Accounts receivable

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.

Concentration of credit risk

Concentration of credit risk - Management routinely assesses the financial strength of its customers and, as a consequence, believes accounts receivable are stated at the net realizable value and credit risk exposure is limited.

Inventory

Inventory - Inventory consists of purchased medical equipment and parts and is stated at the lower of 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.

Property and equipment

Property and equipment – Property and equipment is recorded at cost, net of accumulated depreciation. The costs of additions and betterments are capitalized and expenditures for repairs and maintenance, which do not extend the economic useful life of the related assets, are expensed. The straight-line method of depreciation is used for computing depreciation on property and equipment over the following estimated useful lives:

	Estimated Useful Life
Machines and equipment	3 years
Office and computer equipment	3 years
Medical devices on rent	5 - 15 years
Software	2years
Furniture and fixtures	3 years

Goodwill and Other Intangible Assets

Goodwill and Other Intangible Assets **—** Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company accounts for goodwill under ASC Topic 350, *Intangibles-Goodwill and Other*. The Company tests goodwill for impairment annually, or more frequently whenever events or circumstances indicate impairment may exist. Goodwill is stated at cost less 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 for the year ended December 31, 2021. 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. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The Company has determined that there were no impairment to goodwill or intangible assets for the year ended December 31, 2021.

Impairment of long-lived assets

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. Except for the impairment of the intangible assets discussed above, the Company determined that no impairment of long-lived assets was indicated at December 31, 2021.

Leases

Leases **–** We determine whether an arrangement is a lease at inception. When our lease arrangements include lease and non-lease components, we account 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 sheet, and we recognize 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 our right of use assets and lease liabilities. None of our lease agreements include an option to purchase the leased asset, residual value guarantees, or material restrictive covenants.

Fair value of financial instruments

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.

Preferred stock

Preferred stock – The Company evaluates preferred stock issuances for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determines appropriate equity or liability accounting treatment. Additionally, the Company determines, if classified as equity, whether it would be recorded as permanent or temporary equity.

Sequencing policy

Sequencing policy – The Company follows 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 on the basis of earliest issuance date of potentially dilutive instruments with the earliest grants receiving first allocation of shares.

Convertible instruments and liabilities related to warrants issued

Convertible instruments and liabilities related to warrants issued – 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 ("ECOs") 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 as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. A binomial model was used to estimate the fair value of the ECOs of warrants 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. The expected volatility is estimated based on the actual volatility during the most recent historical period of time equal to the weighted average life of the instruments.

Warrants related to debt issued

Warrants related to debt issued – The Company records a warrant 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 warrant discount is reported as a reduction of the related debt liability.

Beneficial conversion feature on convertible debt

Beneficial conversion feature on convertible debt - The Company records a beneficial conversion feature related convertible 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 in the accompanying Consolidated Statements of Comprehensive Loss. This beneficial conversion feature is reported as a reduction of the related debt liability in the accompanying Consolidated Balance Sheet.

Segment information

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

Revenue Recognition

Revenue Recognition – We recognize revenue in accordance with two different Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") standards: 1) Topic 606 and 2) Topic 842.

Topic 606

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. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under previous U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each

separate performance obligation. In accordance with ASC 606, we apply the following the five-step model:

1. Identify the contract(s) with a customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

2. Identify the performance obligation(s) in the contract. If a contract promises to transfer more than one good or service to a customer, each good or service constitutes a separate performance obligation if the good or service is distinct or capable of being distinct.

3. Determine the transaction price. The transaction price is the amount of consideration to which we expect to be entitled in exchanging the promised goods or services to the customer.

4. Allocate the transaction price to the performance obligations in the contract. For a contract that has more than one performance obligation, we allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which we expect to be entitled in exchange for satisfying each performance obligation.

5. Recognize revenue when (or as) the Company satisfies a performance obligation. For each performance obligation, we determine whether we satisfy the performance obligation at a point in time or over time. Appropriate methods of measuring progress include output methods and input methods.

The Company recognizes revenue primarily from the following types of contracts under ASC 606:

Product Sales and Accessory and Part Sales - Product sales and 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. Device product sales are bundled with an initial one-year warranty and the Company offers a separately priced second-year warranty. The Company allocates the device sales price to the product and the embedded warranty by reference to the stand-alone extended warranty price. Because the warranty represents a stand-ready obligation, revenue is recognized over the time period 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.

Topic 842

The Company recognizes revenue primarily from the following types of contracts under ASC 842:

Rental and Pay per Use Income - Rental revenue represents revenues earned from renting equipment either on a monthly basis or on a pay per use. We account for these rental contracts as operating leases and revenue will be recognized on a straight-line basis in the period billed to the customer. However, under the pay per use agreement, the Company will earn revenues based on the number of times the device is used.

The lease terms are included in our contracts, and the determination of whether our contracts contain leases generally does not require significant assumptions or judgments. In some cases, a rental contract may contain a rental purchase option, whereby the customer has an option to purchase the rented equipment at the end of the term for a specified price. Revenues related to the rental contract will be accounted for as an operating lease as the option to purchase is not reasonably certain to be exercised. Lessees do not provide residual value guarantees on rented equipment.

Shipping and handling costs

Shipping and handling costs - Shipping charges billed to customers are included in revenues. Shipping and handling costs incurred have been recorded in cost of revenues.

Research and development

Research and development - Research and development costs are expensed as incurred. Research and development costs include payments to third parties that specifically relate to the Company's products in clinical development, such as payments to contract research organizations, consulting fees for FDA submissions, universities performing non-medical related research and insurance premiums for clinical studies and non-medical research. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees of the clinical affairs, and research and development departments are classified as research and development costs.

Comprehensive income (loss)

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

Recent Accounting Pronouncements **–**

In August 2020, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity,* which simplifies the accounting for convertible instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature and simplifies the guidance for determining whether a conversion feature is a derivative. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost. These changes will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that was bifurcated according to previously existing rules. In addition, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will be no longer available. The new guidance is effective for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. Effective January 1, 2021, the Company elected to early adopt ASU 2020-06 using the modified retrospective method. The adoption of ASU 2020-06 had no impact on the Company's previously reported financial position or operating results.

In June 2016, the FASB issued 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, which will result 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.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes in several areas including calculating taxes in an interim period, clarifying how to account for taxes that are partially based on income and requiring an entity to reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes

the enactment date. This amendment is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company adopted ASU 2019-12 effective January 1, 2021 with no impact on previously reported financial position or operating results.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment. The amendments in ASU 2017-04 modified the testing that an entity should perform for its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. This amendment is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2017-04 effective January 1, 2021. The adoption of this guidance did not impact our results of operations or financial position.

In May 2021, the FASB issued Accounting Standards Update ("*ASU*") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40).* This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for us on January 1, 2022. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the effect the adoption of this ASU will have on our consolidated financial statements.

Summary of Significant Accounting Policies (Tables)	12 Months Ended Dec. 31, 2021
Summary of Significant Accounting Policies [Abstract]	
Property, Plant and Equipment, Useful Life	The straight-line method of depreciation is used for computing depreciation on property and equipment over the following estimated useful lives:

	Estimated Useful Life
Machines and equipment	3 years
Office and computer equipment	3 years
Medical devices on rent	5 - 15 years
Software	2years
Furniture and fixtures	3 years

Loss per Share (Tables)

12 Months Ended
Dec. 31, 2021

Loss per Share [Abstract]

Weighted Average Shares Outstanding

Accordingly, warrants issued with a $0.01 per share exercise price, are included in weighted average shares outstanding as follows:

	2021	2020
Weighted average shares outstanding		
Common shares	481,619,621	359,880,132
Common shares issuable assuming excercise of nominally priced warrants	36,736,021	18,248,513
Weighted average shares outstanding	518,355,642	378,128,645

Anti-dilutive Equity Securities

Anti-dilutive equity securities consist of the following at December 31, 2021 and 2020, respectively (dollars in thousands):

	2021	2020
Common stock options	31,760	31,938
Common stock purchase warrants	168,192	142,266
Convertible notes payable	90,380	58,657
	290,332	232,861

Asset Purchase Agreement (Tables)

12 Months Ended Dec. 31, 2021

Asset Purchase Agreement [Abstract]

Fair Value of Consideration Exchanged

The tables below present the consideration paid to Celularity and the fair value of the Assets acquired on August 6, 2020 (dollars in thousands):

Purchase Consideration	
Cash paid at closing	$ 18.9
Cash paid pursuant to letter of intent	1.1
Note payable to seller	4.0
Total Consideration	$ 24.0

Fair Value of Net Assets Acquired	
Inventory	$ 1.9
Property and equipment	0.4
Intangible assets (1)	14.4
Goodwill (2)	7.3
Total fair value of net assets acquired	$ 24.0

1. Intangible assets, as summarized below, are recorded at their estimated fair value. The estimated fair value of the acquired customer relationships is determined using the multi-period excess earnings method. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The estimated fair value of the acquired patent and trade names is based on a relief from royalty method. The estimated useful lives for intangible assets were determined based on the remaining useful economic lives of the intangible assets that are expected to contribute directly or indirectly to future cash flows.

2. Goodwill represents the excess of the total purchase consideration over fair value of the assets recognized and represents the future economic benefits that we believe will result from combining the operations of SANUWAVE and UltraMIST®, including expected future synergies and operating efficiencies. Goodwill resulting from the Transaction has been assigned to the Company's lone operating segment. Goodwill is not subject to amortization and is tested for impairment annually and whenever events or changes in circumstances indicate that impairment may have occurred. The goodwill recognized is expected to be deductible for income tax purposes (dollars in thousands).

Estimates of Fair Value of Assets Acquired

Intantible Assets	**Fair Value**	**Useful Life (Years)**
Customer relationships - UltraMIST®	$ 3.8	7
Customer relationahips - Biologics	7.6	7
Patent	2.3	19
Trade names	0.7	19
Total intangible assets	$ 14.4	

Pro forma Information

The pro forma financial information does not reflect revenue opportunities and cost savings which the Company expected to realize as a result of the acquisition or estimates of charges related to the integration activity.

	Year Ended December 31 (unaudited)
	2020
Total revenues	$ 7.8
Net Loss	(35.6)

Inventory (Tables)

12 Months Ended
Dec. 31, 2021

Inventory [Abstract]

Inventory

Inventory consists of the following at December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Inventory - finished goods	$ 335	$ 1,146
Inventory - parts and accessories	705	1,810
Total inventory	$ 1,040	$ 2,956

Property and Equipment (Tables)	12 Months Ended Dec. 31, 2021
Property and Equipment [Abstract]	
Property and Equipment	Property and equipment consists of the following at December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Machines and equipment	$ 190	$ 278
Office and computer equipment	316	245
Medical devices on rent	806	513
Software	38	38
Furniture and fixtures	27	23
Other assets	102	3
Total	1,479	1,100
Accumulated depreciation	(811)	(629)
Net property and equipment	$ 668	$ 471

Goodwill and Other Intangible Assets (Tables)	12 Months Ended Dec. 31, 2021
Goodwill and Other Intangible Assets [Abstract]	
Carrying Value of Goodwill and Other Intangible Assets	Changes in the carrying value of goodwill and other intangible assets during the year ended December 31, 2021 consist of the following activity:

	December 31, 2020	Amortization	Impairment	December 31, 2021	Weighted average useful life (in years)
Goodwill	$ 7,260	$ -	$ -	$ 7,260	-
Intangible assets subject to amortization					
Customer relationships - UltraMIST	$ 3,603	$ (546)	$ -	$ 3,057	2.9
Patent	2,263	(121)	-	2,142	6.4
Trade names	679	(37)	-	642	1.9
Other intangible assets	$ 6,545	$ (704)	$ -	$ 5,841	3.8

Future Amortization Expense

Future amortization expense is expected to be the following:

Year ending December 31,	Amortization
2022	704
2023	704
2024	704
2025	704
2026	704
Thereafter	2,321
	$ 5,841

Accrued Expenses (Tables)

12 Months Ended
Dec. 31, 2021

Accrued Expenses [Abstract]

Components of Accrued Expenses Accrued expenses consist of the following at December 31, 2021 and 2020:

	2021	2020
Registration penalties	$ 1,950	$ 264
License fees	893	336
Board of director's fees	507	320
Legal and professional fees	221	196
Other	823	1,011
	$ 4,394	$ 2,127

Revenue (Tables)

12 Months Ended
Dec. 31, 2021

Revenue [Abstract]

Disaggregation of Revenue

The disaggregation of revenue is based on geographical region. The following table presents revenue from contracts with customers for the years ended December 31, 2021 and 2020 (dollars in thousands):

	Year ended December 31, 2021			Year ended December 31, 2020		
	United States	International	Total	United States	International	Total
Accessory and parts revenue	$ 7,770	$ 302	$ 8,072	$ 1,121	$ 88	$ 1,209
Product	2,766	350	3,116	2,179	88	2,267
License fees and other	135	60	195	-	152	152
Topic 606 Revenue	$ 10,671	$ 712	$ 11,383	$ 3,300	$ 328	$ 3,628
Rental income	1,627	-	1,627	429	-	429
Topic 842 Revenue	$ 1,627	$ -	$ 1,627	$ 429	$ -	$ 429
Total Revenue	$ 12,298	$ 712	$ 13,010	$ 3,729	$ 328	$ 4,057

Contract Liabilities

As of December 31, 2021 and 2020, the Company has contract liabilities from contracts with customers as follows (dollars in thousands):

	December 31, 2021	December 31, 2020
Service agreements	$ 137	$ 69
Deposit on future equipment purchases	204	-
Total contract liabilities	341	69
Less: current portion	(48)	(32)
Non-current contract liabilities	$ 293	$ 37

The following table summarizes the changes in contract liabilities during the year ended December 31, 2021 and 2020 (dollars in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020
Beginning balance	$ 69	$ 128
New service agreement additions	100	2
Deposit on future equipment purchases	204	-
Revenue recognized	(32)	(61)
Total contract liabilities	341	69
Less current portion	(48)	(32)
Non-current contract liabilities	$ 293	$ 37

Concentration of Credit Risk and Limited Suppliers (Tables)

12 Months Ended

Dec. 31, 2021

Concentration of Credit Risk and Limited Suppliers [Abstract]

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 for the ended December 31, 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
Accounts Receivable:		
Customer A	24%	n/a
Customer B	16%	46%

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 for the years ended December 31, 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
Purchases:		
Vendor A	50%	n/a
Vendor B	21%	n/a
Vendor C	n/a	35%
Vendor D	n/a	22%
Vendor E	n/a	11%

Accounts Receivable Factoring (Tables)	12 Months Ended Dec. 31, 2021
Accounts Receivable Factoring [Abstract]	
Accounts Receivable Factoring	
Receivable amount transferred at 12/31/2021	2,026
Reserve amount held	(289)
Funds due to factoring at 12/31/2021	1,737

Notes Payable (Tables)

12 Months Ended
Dec. 31, 2021

Notes Payable [Abstract]

Outstanding Notes Payable

The following two tables summarize outstanding notes payable as of December 31, 2021 and December 31, 2020 (in thousands):

	Maturity Date	Interest Rate	Conversion Price	Principal	Remaining Debt Discount	Remaining Embedded Conversion Option	Carrying Value
Senior secured promissory note payable, in default	In default	20.25%	n/a	$ 15,000	(3,414)	-	$ 11,586
Convertible promisory notes payable, in default	In default	15.4%	$ 0.1071	6,445	(1,099)	6,255	11,601
Convertible promisory notes payable, related parties, in default	In default	14.0%	$ 0.10	1,596	-	-	1,596
SBA loan #2	February 20, 2026	1.00%	n/a	1,033	-	-	1,033
Advances on future cash receipts	March 11, 2022	n/a	n/a	1,500	(1,054)	-	446
Total debt outstanding, including amounts in default				25,574	(5,567)	6,255	26,262
Less: current maturities, including notes in default				(24,699)	5,567	(6,255)	(25,387)
Total long-term debt as of December 31, 2021				$ 875	$ -	$ -	$ 875

	Maturity Date	Stated Interest Rate	Conversion Price	Principal	Remaining Debt Discount	Carrying Value
Senior secured promissory note payable, in default	In default	20.25%	n/a	$ 15,000	(4,324)	$ 10,676
Convertible promissory notes payable, in default:						
Seller Note	In default	17.00%	$ 0.10	4,000	-	4,000
Convertible promissory notes payable, related parties, in default:						
Convertible promissory notes (HealthTronics), related parties	In default	14.0%	$ 0.10	1,596	-	1,596
SBA loan #1	May 28, 2022	1.00%	n/a	464	-	464
Total debt outstanding, including amounts in default				21,060	(4,324)	16,736
Less: current maturities, including notes in default				(20,917)	4,324	(16,593)
Total long-term debt as of December 31, 2020				$ 143	$ -	$ 143

Fair Value of Conversion Option liability

The disbursements made in April, May and September 2021 under the Leviston Notes and the Five Institutions' Notes included a Conversion Option that meets the definition of a derivative liability and, accordingly, is required to be bifurcated. The fair value of Conversion Option liability was determined by using a binomial pricing model (dollars in thousands):

Valuation at December 31, 2021	Principal	Conversion Price[(1)]	Interest Rate (annual) [(2)]	Volatility (annual) [(3)]	Time to Maturity (Years)	Fair Value of Conversion Option
Leviston Issuances	$ 1,902	0.109	0.16%	303.20%	0.4	$ 5,204
Five Institution Issuances	544	0.109	0.26%	249.00%	0.7	1,051
	$ 2,446					$ 6,255

(1) Based on the terms provided in the warrant agreement to purchase common stock of the Company as of December 31, 2021.
(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.

Valuation at issue dates	Conversion	Interest Rate	Volatility	Time to Maturity	Fair Value of

	Principal	Price[1]	(annual) [2]	(annual) [3]	(Years)	Conversion Option
Leviston Issuances	$ 1,902	0.18	0.07%	73.10%	1.0	$ 3,206
Five Institution Issuances	544	0.18	0.08%	80.10%	1.0	932
	$ 2,446					$ 4,138

(1) Based on the terms provided in the warrant agreement to purchase common stock of the Company on the stated issuance dates.

(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.

Common Stock Purchase Warrants (Tables)

12 Months Ended Dec. 31, 2021

Common Stock Purchase Warrants [Abstract]

Warrant Activity

A summary of the warrant activity during the years December 31, 2021 and 2020 is as follows:

	Warrants	Weighted Average Exercise Price per share	Weighted Average Remaining Contractual Life (years)
Warrants at December 31, 2019	9,474,091	$ 0.11	5.03
Issuances	189,182,645	0.19	
Exercised	(8,200,000)	0.10	
Forfeited or expired	(100,000)	0.20	
Outstanding at December 31, 2020	190,356,736	$ 0.19	3.43
Issuances	25,925,928	0.18	
Exercised	(11,400,000)	0.01	
Forfeited or expired	-	-	
Outstanding at December 31, 2021	204,882,664	$ 0.20	2.54

Fair Value Measurements (Tables)

12 Months Ended Dec. 31, 2021

Fair Value Measurements [Abstract]

Liabilities Measured at Fair Value on Recurring Basis

The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy as of December 31, 2021 and 2020 (in thousands):

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

	Fair value measured at December 31, 2020			
	Fair value at December 31, 2020	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 8,855	-	-	8,855
Embedded conversion option	-	-	-	-
Total fair value	8,855	-	-	8,855

Warrants Outstanding and Fair Values

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2021 and 2020. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g. changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs (in thousands):

	Warrant Liability	Embedded Conversion Feature	Total
Balance December 31, 2019	$ -	$ -	$ -
Warrants classified as liabilities	11,955	-	11,955
Warrants reclassified as equity	(6,293)	-	(6,293)
Change in fair value	3,193	-	3,193
Balance December 31, 2020	$ 8,855	$ -	$ 8,855
Cashless exercise	(2,030)	-	(2,030)
Warrants classified as liabilities	2,282	-	2,282
Transfer to convertible feature	-	4,139	4,139
Change in fair value	507	2,116	2,623
Balance December, 2021	$ 9,614	$ 6,255	$ 15,869

A summary of the warrant liability activity for the year ended December 31, 2021 is as follows:

	Warrants Outstanding	Fair Value per Share	Fair Value
Balance December 31, 2019	-	$ -	$ -
Warrants classified as liabilities	112,210,902	0.11	11,955,454
Warrants reclassified as Equity	(64,119,742)	0.10	(6,292,695)
Gain on remeasurement of warrant liability	-		3,192,620
Balance December 31, 2020	48,091,160	$ 0.18	$ 8,855,379
Cashless exercise of LGH Warrants	(11,400,000)	0.18	(2,030,052)
Warrants classified as liabilities	25,926,028	0.10	2,282,262
Gain on remeasurement of warrant liability	-		506,545
Balance December, 2021	62,617,188	$ 0.15	$ 9,614,134

Fair Value of Warrant Liabilities Using Black-Scholes Model

Significant Black Scholes valuation model inputs related to the Company's different Warrants at December 31, 2021 and 2020 are listed below.

	2021	2020
Weighted average expected life in years	4.67	7.00
Weighted average volatility	116%	121%
Weighted average risk free interest rate	1.2%	0.5%
Expected dividend yield	0.00%	0.00%

Leases (Tables)

12 Months Ended
Dec. 31, 2021

Leases [Abstract]

Summary of ROU Assets and Lease Liabilities

The following is a summary of the Company's right of use assets and lease liabilities at December, 2021 and 2020 (in thousands):

	December 31, 2021			December 31, 2020		
	Operating Leases	Financing Leases	Total	Operating Leases	Financing Leases	Total
Right of use assets	$ 725	$ 626	$ 1,351	$ 725	$ 644	$1,369
Less: Accumulated amortization	(574)	(433)	(1,007)	(339)	(235)	(574)
Right of use assets, net	$ 151	$ 193	$ 344	$ 386	$ 409	$ 795
Lease liabilities	$ 157	$ 229	$ 386	$ 415	$ 427	$ 842
Less: current portion	(83)	(185)	(268)	(257)	(194)	(451)
Lease Liabilities	$ 74	$ 44	$ 118	$ 158	$ 233	$ 391

Lease Costs

Total lease costs for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	2021	2020
Finance lease costs:		
Amortization of right-of-use assets	$ 217	$ 94
Interest on lease liabilities	41	33
Operating lease costs	350	118
Total lease costs	$ 608	$ 245

Cash Paid for Amounts Included in Measurement of Lease Liabilities

The following summarizes cash paid for amounts included in the measurement of lease liabilities as well as the related right-of-use assets obtained for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from finance leases	$ (234)	$ (103)
Operating cash flows from operating leases	$ (350)	$ (118)

Operating Leases, Maturities

As of December 31, 2021, the maturities of the Company's operating lease liability, which have initial or remaining lease terms in excess of one year, consist of the following (in thousands):

	Amount
Year ending December 31,	
2022	$ 96
2023	68
2024	11
Total lease payments	175
Less: Present value adjustment	(18)
Lease liability	$ 157

Finance Lease, Maturities

As of December 31, 2021, the maturities of the Company's financing lease liability, which have initial or remaining lease terms in excess of one year, consist of the following (in thousands):

	Amount
Year ending December 31,	
2022	$ 200
2023	18
Total lease payments	218
Present value adjustment	11

Lease liability	$ 229

Stock-based Compensation (Tables)

12 Months Ended Dec. 31, 2021

Stock-based Compensation [Abstract]

Stock Incentive Plan Activity

The following is a summary of the activity of the Stock Incentive Plan for the years ended December 31, 2021 and 2020:

	Options	Weighted Average Exercise Price per share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	34,303,385	$ 0.28	6.62	$ 981,088
Granted	100,000	0.26		
Exercised	(325,000)	0.15		
Forfeited or expired	(2,140,000)	0.71		
Outstanding at December 31, 2020	31,938,385	0.26	5.94	$ 1,372,116
Granted	-	-		
Exercised	-	-		
Forfeited or expired	(179,000)	0.18		
Outstanding at December 31, 2021	31,759,385	0.26	4.92	$ 1,056,236
Vested and exercisable at December 31, 2021	31,409,385	$ 0.26	4.92	$ 1,056,236

Weighted Average Assumptions

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions for the year ended December 31, 2020 is shown below:

	2020
Weighted average expected life in years	5.00
Weighted average volatility	124%
Weighted average risk free interest rate	1.6%
Expected dividend yield	0.00%

Income taxes (Tables)

12 Months Ended
Dec. 31, 2021

Income taxes [Abstract]

Components of Income Tax Expense (Benefit)

The components of the net loss before income taxes for the years ended December 31, 2021 and 2020 are as follows (dollars in thousands):

	2021	2020
Domestic	$ (27,208)	$ (30,945)
Foreign	(23)	8
Net loss before income taxes	$ (27,231)	$ (30,937)

The income tax provision (benefit) from continuing operations consists of the following at December 31, 2021 and 2020 (dollars in thousands):

Current:	2021	2020
Federal	$ -	$ -
State	28	-
Foreign	-	-
	28	-
Deferred:		
Federal	(5,038)	(5,420)
State	(869)	(964)
Foreign	4	1
Change in valuation allowance	5,903	6,383
	$ 28	$ -

Effective Income Tax Reconciliation

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, 2021 and 2020 to pretax loss from operations as a result of the following for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Tax expense (benefit) at statutory rate	$ (5,718)	$ (6,498)
Increase (reduction) in income taxes resulting from:		
State income taxes (benefits), net of federal benefit	(837)	(913)
Non-deductible gain on warrant adjustment valuation	417	670
Income from foreign subsidiaries	-	2
Change in valuation allowance	5,903	6,383
Registration penalties	354	-
Other	(91)	356
Income tax expense (benefit)	$ 28	$ -

Schedule of Deferred Tax Assets and Liabilities

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2021 and 2020 are as follows (dollars in thousands):

	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 33,238	$ 28,048
Net operating loss carryforwards - foreign	23	19
Excess of tax basis over book value of property and equipment	14	8
Excess of tax basis over book value of intangible assets	1,632	1,811
Stock-based compensation	1,613	1,613
Accrued employee compensation	698	427
Capitalized equity costs	49	49
Net change in reserve accounts	898	287
	38,165	32,262
Valuation allowance	(38,165)	(32,262)

Net deferred tax asset	$ -	$ -

Nature of the Business and Basis of Presentation (Details) $ in Thousands	Dec. 31, 2021 USD ($)	Dec. 31, 2020 USD ($)	Aug. 06, 2020 Product Technology
Nature of the Business and Basis of Presentation [Abstract]			
Number of highly complementary and market-cleared energy transfer technologies | Technology			2
Number of human tissue biologic products | Product			2
Reclassification [Abstract]			
Accrued expenses	$ 4,394	$ 2,127	
Accrued employee compensation	$ 4,247	2,541	
Reclassification, Adjustment [Member]			
Reclassification [Abstract]			
Accrued expenses		(154)	
Accrued employee compensation		$ 154	

Summary of Significant Accounting Policies, Property and Equipment (Details)	12 Months Ended Dec. 31, 2021
Machines and Equipment [Member]	
Depreciation of Property and Equipment [Abstract]	
Estimated useful lives	3 years
Office and Computer Equipment [Member]	
Depreciation of Property and Equipment [Abstract]	
Estimated useful lives	3 years
Medical Devices On Rent [Member] | Minimum [Member]	
Depreciation of Property and Equipment [Abstract]	
Estimated useful lives	5 years
Medical Devices On Rent [Member] | Maximum [Member]	
Depreciation of Property and Equipment [Abstract]	
Estimated useful lives	15 years
Software [Member]	
Depreciation of Property and Equipment [Abstract]	
Estimated useful lives	2 years
Furniture and Fixtures [Member]	
Depreciation of Property and Equipment [Abstract]	
Estimated useful lives	3 years

Summary of Significant Accounting Policies, Goodwill and Other Intangible Assets (Details) $ in Thousands	12 Months Ended Dec. 31, 2021 USD ($)
Goodwill and Other Intangible Assets [Abstract]	
Impairment on goodwill	$ 0
Impairment on other intangible assets	$ 0
Customer Relationships [Member]	
Goodwill and Other Intangible Assets [Abstract]	
Estimated weighted average life	7 years
Patents [Member]	
Goodwill and Other Intangible Assets [Abstract]	
Estimated weighted average life	19 years
Tradenames [Member]	
Goodwill and Other Intangible Assets [Abstract]	
Estimated weighted average life	19 years

Summary of Significant Accounting Policies, Impairment of Long-lived Assets (Details) $ in Thousands	12 Months Ended Dec. 31, 2021 USD ($)
Impairment of long-lived assets [Abstract]	
Impairment of long-lived assets	$ 0

Summary of Significant Accounting Policies, Segment Information (Details)	12 Months Ended Dec. 31, 2021 Segment
Segment Information [Abstract]	
Number of operating segments	1

Summary of Significant Accounting Policies, Revenue Recognition (Details)	12 Months Ended Dec. 31, 2021
Revenue Recognition [Abstract]	
Initial warranty period of device product	1 year
Extended warranty period of device product	1 year

Loss per Share, Weighted Average Shares Outstanding (Details) - $ / shares	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Weighted Average Shares Outstanding [Abstract]		
Weighted average shares outstanding (in shares)	518,355,642	378,128,645
Warrant exercise price (in dollars per share)	$ 0.01	$ 0.10
Common Shares [Member]		
Weighted Average Shares Outstanding [Abstract]		
Weighted average shares outstanding (in shares)	481,619,621	359,880,132
Common Shares Issuable Assuming Exercise of Nominally Priced Warrants [Member]		
Weighted Average Shares Outstanding [Abstract]		
Weighted average shares outstanding (in shares)	36,736,021	18,248,513

Loss per Share, Anti Dilutive Equity Securities (Details) - shares shares in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Anti-dilutive Securities [Abstract]		
Anti-dilutive equity securities (in shares)	290,332	232,861
Common Stock Options [Member]		
Anti-dilutive Securities [Abstract]		
Anti-dilutive equity securities (in shares)	31,760	31,938
Warrants Classified [Member]		
Anti-dilutive Securities [Abstract]		
Anti-dilutive equity securities (in shares)	168,192	142,266
Convertible Notes Payable [Member]		
Anti-dilutive Securities [Abstract]		
Anti-dilutive equity securities (in shares)	90,380	58,657

Asset Purchase Agreement, Purchase Consideration (Details) - USD ($) $ in Thousands	Aug. 06, 2020	Dec. 31, 2021	Dec. 31, 2020
Asset Purchase Agreement [Abstract]			
Accrued license fees		$ 893	$ 336
Celularity's UltraMIST Assets [Member]			
Asset Purchase Agreement [Abstract]			
Initial term of license agreement	5 years		
License agreement automatic renewal term	1 year		
Written notice required prior to expiration of current term	180 days		
Upfront royalty payments	$ 446		
Accrued license fees		$ 893	$ 336
Purchase Consideration [Abstract]			
Cash paid at closing	18,900		
Previous cash deposit pursuant to letter of intent	1,100		
Note payable to seller	4,000		
Total consideration	$ 24,000		

Asset Purchase Agreement, Estimates of Fair Value of Assets Acquired (Details) $ in Millions	Aug. 06, 2020 USD ($)	
Net Assets Acquired [Abstract]		
Inventory	$ 1.9	
Property, plant and equipment	0.4	
Intangible assets	14.4	[1]
Goodwill	7.3	[2]
Total	24.0	
Celularity's UltraMIST Assets [Member]		
Net Assets Acquired [Abstract]		
Intangible assets	$ 14.4	

[1] Intangible assets, as summarized below, are recorded at their estimated fair value. The estimated fair value of the acquired customer relationships is determined using the multi-period excess earnings method. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The estimated fair value of the acquired patent and trade names is based on a relief from royalty method. The estimated useful lives for intangible assets were determined based on the remaining useful economic lives of the intangible assets that are expected to contribute directly or indirectly to future cash flows.

[2] Goodwill represents the excess of the total purchase consideration over fair value of the assets recognized and represents the future economic benefits that we believe will result from combining the operations of SANUWAVE and UltraMIST®, including expected future synergies and operating efficiencies. Goodwill resulting from the Transaction has been assigned to the Company’s lone operating segment. Goodwill is not subject to amortization and is tested for impairment annually and whenever events or changes in circumstances indicate that impairment may have occurred. The goodwill recognized is expected to be deductible for income tax purposes (dollars in thousands).

Asset Purchase Agreement, Estimated Useful Lives for Intangible Assets (Details) - USD ($) $ in Millions	Aug. 06, 2020	12 Months Ended Dec. 31, 2021
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated fair value	[1] $ 14.4	
Customer Relationships [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated weighted average life		7 years
Patent [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated weighted average life		19 years
Celularity's UltraMIST Assets [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated fair value	14.4	
Celularity's UltraMIST Assets [Member] | Customer Relationships [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated fair value	$ 3.8	
Estimated weighted average life	7 years	
Celularity's UltraMIST Assets [Member] | Patent [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated fair value	$ 2.3	
Estimated weighted average life	19 years	
Celularity's UltraMIST Assets [Member] | Tradenames [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated fair value	$ 0.7	
Estimated weighted average life	19 years	
Biologics [Member] | Customer Relationships [Member]		
Estimated Useful Lives for Intangible Assets [Abstract]		
Estimated fair value	$ 7.6	
Estimated weighted average life	7 years	

[1] Intangible assets, as summarized below, are recorded at their estimated fair value. The estimated fair value of the acquired customer relationships is determined using the multi-period excess earnings method. At December 31, 2020, the Company determined that intangible assets related to certain customer relationships was impaired. See Note 8 for additional discussion of this impairment. The estimated fair value of the acquired patent and trade names is based on a relief from royalty method. The estimated useful lives for intangible assets were determined based on the remaining useful economic lives of the intangible assets that are expected to contribute directly or indirectly to future cash flows.

Asset Purchase Agreement, Acquisition and Related Costs (Details) $ in Millions	12 Months Ended Dec. 31, 2021 USD ($)
Celularity's UltraMIST Assets [Member] | Acquisition and Related Costs [Member]	
Acquisition and Related Costs [Abstract]	
Acquisition costs	$ 1.1

Asset Purchase Agreement, Unaudited Actual and Pro forma Information (Details) - USD ($) $ in Thousands	5 Months Ended	12 Months Ended	
	Dec. 31, 2020	Dec. 31, 2021	Dec. 31, 2020
Unaudited Actual and Pro forma Information [Abstract]			
Total revenues		$ 11,383	$ 3,628
Operating income		$ (14,142)	(25,200)
Pro Forma Information [Abstract]			
Total revenues			7,800
Net loss			$ (35,600)
Celularity's UltraMIST Assets [Member]			
Unaudited Actual and Pro forma Information [Abstract]			
Total revenues	$ 3,600		
Operating income	$ 467		

Inventory (Details) - USD ($) $ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Inventory, Net [Abstract]		
Inventory - finished goods	$ 335	$ 1,146
Inventory - parts and accessories	705	1,810
Total inventory	$ 1,040	$ 2,956

Property and Equipment (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Property and Equipment [Abstract]		
Property and equipment, gross	$ 1,479	$ 1,100
Accumulated depreciation	(811)	(629)
Property and equipment, net	668	471
Depreciation expense	182	98
Machines and Equipment [Member]		
Property and Equipment [Abstract]		
Property and equipment, gross	190	278
Office and Computer Equipment [Member]		
Property and Equipment [Abstract]		
Property and equipment, gross	316	245
Medical Devices On Rent [Member]		
Property and Equipment [Abstract]		
Property and equipment, gross	806	513
Software [Member]		
Property and Equipment [Abstract]		
Property and equipment, gross	38	38
Furniture and Fixtures [Member]		
Property and Equipment [Abstract]		
Property and equipment, gross	27	23
Other Assets [Member]		
Property and Equipment [Abstract]		
Property and equipment, gross	$ 102	$ 3

Goodwill and Other Intangible Assets (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Goodwill [Roll Forward]		
Goodwill, beginning balance	$ 7,260	
Goodwill, impairment	0	
Goodwill, ending balance	7,260	$ 7,260
Intangible assets subject to amortization [Roll Forward]		
Other intangible assets, beginning balance	6,545	
Amortization	(704)	(713)
Impairment	0	7,200
Other intangible assets, ending balance	$ 5,841	6,545
Other intangible assets, Weighted average useful life	3 years 9 months 18 days	
Future Amortization Expense [Abstract]		
2022	$ 704	
2023	704	
2024	704	
2025	704	
2026	704	
Thereafter	2,321	
Total	5,841	
Customer Relationships [Member] | Celularity's UltraMIST Assets [Member]		
Intangible assets subject to amortization [Roll Forward]		
Other intangible assets, beginning balance	3,603	
Amortization	(546)	
Impairment	0	
Other intangible assets, ending balance	$ 3,057	3,603
Other intangible assets, Weighted average useful life	2 years 10 months 24 days	
Patent [Member]		
Intangible assets subject to amortization [Roll Forward]		
Other intangible assets, beginning balance	$ 2,263	
Amortization	(121)	
Impairment	0	
Other intangible assets, ending balance	$ 2,142	2,263
Other intangible assets, Weighted average useful life	6 years 4 months 24 days	
Trade Names [Member]		
Intangible assets subject to amortization [Roll Forward]		
Other intangible assets, beginning balance	$ 679	
Amortization	(37)	
Impairment	0	
Other intangible assets, ending balance	$ 642	$ 679

Other intangible assets, Weighted average useful life	1 year 10 months 24 days

Accrued Expenses (Details) - USD ($) $ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Accrued Expense [Abstract]		
Registration penalties	$ 1,950	$ 264
License fees	893	336
Board of director's fees	507	320
Legal and professional fees	221	196
Other	823	1,011
Total accrued expenses	$ 4,394	$ 2,127

Revenue, Disaggregation of Revenue (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Disaggregation of Revenue [Abstract]		
Revenue	$ 11,383	$ 3,628
Rental income	1,627	429
Total Revenue	13,010	4,057
Accessory and Parts Revenue [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	8,072	1,209
Product [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	3,116	2,267
Total Revenue	3,116	2,267
License Fees and Other [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	195	152
United States [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	10,671	3,300
Rental income	1,627	429
Total Revenue	12,298	3,729
United States [Member] | Accessory and Parts Revenue [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	7,770	1,121
United States [Member] | Product [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	2,766	2,179
United States [Member] | License Fees and Other [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	135	0
International [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	712	328
Rental income	0	0
Total Revenue	712	328
International [Member] | Accessory and Parts Revenue [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	302	88
International [Member] | Product [Member]		
Disaggregation of Revenue [Abstract]		
Revenue	350	88
International [Member] | License Fees and Other [Member]		

Disaggregation of Revenue [Abstract]		
Revenue	$ 60	$ 152

Revenue, Contract Liabilities (Details) - USD ($) $ in Thousands	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Contract liabilities [Abstract]			
Total contract liabilities	$ 341	$ 69	$ 128
Less: current portion	(48)	(32)	
Non-current contract liabilities	293	37	
Revenue related to contract liabilities	(32)	(61)	
New Service Agreement Additions [Member]			
Contract liabilities [Abstract]			
Total contract liabilities	100	2	
Deposit on Future Equipment Purchases [Member]			
Contract liabilities [Abstract]			
Total contract liabilities	204	0	
Service Agreements [Member]			
Contract liabilities [Abstract]			
Total contract liabilities	$ 137	$ 69	

Concentration of Credit Risk and Limited Suppliers (Details)	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Accounts Receivable [Member] | Customer Concentration Risk [Member] | Customer A [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage	24.00%	
Accounts Receivable [Member] | Customer Concentration Risk [Member] | Customer B [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage	16.00%	46.00%
Purchases [Member] | Supplier Concentration Risk [Member] | Vendor A [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage	50.00%	
Purchases [Member] | Supplier Concentration Risk [Member] | Vendor B [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage	21.00%	
Purchases [Member] | Supplier Concentration Risk [Member] | Vendor C [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage		35.00%
Purchases [Member] | Supplier Concentration Risk [Member] | Vendor D [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage		22.00%
Purchases [Member] | Supplier Concentration Risk [Member] | Vendor E [Member]		
Concentration of Credit Risk and Limited Suppliers [Abstract]		
Concentration risk, percentage		11.00%

Accounts Receivable Factoring (Details) - USD ($) $ in Thousands	Jun. 17, 2021	Dec. 31, 2021	Dec. 31, 2020
Accounts Receivable Factoring [Abstract]			
Receivable amount transferred at 12/31/2021		$ 2,026	
Reserve amount held		(289)	
Funds due to factoring at 12/31/2021		1,737	
Accounts Receivable Factoring [Abstract]			
Accounts receivable		$ 2,415	$ 2,356
Accounts Receivable Factoring Agreement with Goodman [Member]			
Accounts Receivable Factoring [Abstract]			
Percentage of accounts receivable	86.25%		
Interest fixed funding annualized rate	15.00%		
Period, interest fixed funding annualized rate	30 days		
Interest fixed funding thereafter annualized rate	14.40%		
Agreement term	1 month		
Automatic renewal period of agreement	1 month		
Period of notice termination	30 days		
Accounts Receivable Factoring Agreement with Goodman [Member] | Maximum [Member]			
Accounts Receivable Factoring [Abstract]			
Accounts receivable	$ 3,000		

Notes Payable, Outstanding Notes Payable (Details) - USD ($) $ / shares in Units, $ in Thousands	12 Months Ended Dec. 31, 2021	Feb. 20, 2021	Dec. 31, 2020
Senior Secured Promissory Notes Payable [Abstract]			
Long-term debt gross	$ 25,574		$ 21,060
Long-term debt gross, current	(24,699)		(20,917)
Long-term debt gross, noncurrent	875		143
Remaining debt discount	(5,567)		(4,324)
Senior secured promissory note payable, in default	11,586		10,676
Remaining debt discount, current	5,567		4,324
Remaining debt discount, noncurrent	0		0
Remaining embedded conversion option	6,255		
Remaining embedded conversion option, current	(6,255)		
Remaining embedded conversion option, noncurrent	0		
Convertible promissory note payable, in default	11,601		4,000
Advances on future cash receipts	446		0
Debt, Long-term and Short-term, Combined Amount [Abstract]			
Long-term debt net	26,262		16,736
Long-term debt net, current	(25,387)		(16,593)
Long-term debt net, noncurrent	$ 875		$ 143
Convertible Notes Payable [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	In default		
Stated interest rate	14.00%		
Conversion price (in dollars per share)	$ 0.10		
Principal amount	$ 1,596		
Remaining debt discount	0		
Remaining embedded conversion option	0		
Convertible promissory notes payable, related parties, in default	$ 1,596		
Convertible Notes Payable [Member] | Health Tronics [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	In default		
Stated interest rate			14.00%
Conversion price (in dollars per share)			$ 0.10
Principal amount			$ 1,596
Remaining debt discount			0
Convertible promissory notes payable, related parties, in default			$ 1,596
SBA Loan #1 [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	May 28, 2022		
Stated interest rate			1.00%

Principal amount			$ 464
Remaining debt discount			0
SBA loans			$ 464
SBA Loan #2 [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	Feb. 20, 2026		
Stated interest rate	1.00%	1.00%	
Principal amount	$ 1,033		
Remaining debt discount	0		
Remaining embedded conversion option	0		
SBA loans	$ 1,033		
Advances on Future Cash Receipts [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	Mar. 11, 2022		
Principal amount	$ 1,500		
Remaining debt discount	(1,054)		
Remaining embedded conversion option	0		
Advances on future cash receipts	$ 446		
Senior Secured Note [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	In default		
Stated interest rate	20.25%		20.25%
Principal amount	$ 15,000		$ 15,000
Remaining debt discount	(3,414)		(4,324)
Senior secured promissory note payable, in default	11,586		$ 10,676
Remaining embedded conversion option	$ 0		
Convertible Debt [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	In default		
Stated interest rate	15.40%		
Conversion price (in dollars per share)	$ 0.1071		
Principal amount	$ 6,445		
Remaining debt discount	(1,099)		
Remaining embedded conversion option	6,255		
Convertible promissory note payable, in default	$ 11,601		
Convertible Debt [Member] | Seller Note [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Maturity date	In default		
Stated interest rate			17.00%
Conversion price (in dollars per share)			$ 0.10
Principal amount			$ 4,000
Remaining debt discount			0
Convertible promissory note payable, in default			$ 4,000

Notes Payable, Senior Secured Promissory Note Payable, in Default (Details) - USD ($) $ in Thousands	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Aug. 06, 2020
Senior Secured Promissory Notes Payable [Abstract]			
Accrued interest	$ 2,521	$ 1,021	
Interest expense	$ 6,883	2,025	
Senior Secured Note and Warrants [Member] | NH Expansion Credit Fund Holdings LP [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Principal amount			$ 15,000
Additional default accrued interest rate	5.00%		
Senior Secured Note [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Principal amount	$ 15,000	15,000	
Senior Secured Note [Member] | NH Expansion Credit Fund Holdings LP [Member]			
Senior Secured Promissory Notes Payable [Abstract]			
Amortization expense	910		
Accrued interest	1,600	642	
Interest expense	$ 3,100	$ 1,500	

Notes Payable, Convertible Promissory Notes Payable, in Default (Details) - USD ($) $ in Thousands	12 Months Ended		
	Aug. 06, 2020	Dec. 31, 2021	Dec. 31, 2020
Debt Instruments [Abstract]			
Accrued interest		$ 2,521	$ 1,021
Celularity's UltraMIST Assets [Member] | Seller Note [Member]			
Debt Instruments [Abstract]			
Paid for assets	$ 24,000		
Issuance of promissory notes	$ 4,000		
Maturity date		Aug. 06, 2021	
Accrued interest rate	5.00%		
Interest rate percentage	12.00%		
Accrued interest		$ 761	$ 192

Notes Payable, April 2021 Securities Purchase Agreement and Warrants (in Default) (Details) $ / shares in Units, $ in Thousands	Sep. 03, 2021 USD ($) Investors	May 14, 2021 USD ($)	Apr. 21, 2021 USD ($)	Apr. 20, 2021 USD ($) $ / shares shares	12 Months Ended Dec. 31, 2021 USD ($) $ / shares	Dec. 31, 2020 USD ($) $ / shares	Dec. 31, 2019 $ / shares
April 2021 Securities Purchase Agreement and Warrants [Abstract]							
Warrant exercise price (in dollars per share) | $ / shares					$ 0.20	$ 0.19	$ 0.11
Proceeds from, promissory note disbursement					$ 940	$ 13,347	
Accrued interest					2,521	1,021	
Interest expense					6,883	$ 2,025	
April 2021 Securities Purchase Agreement and Warrants [Member]							
April 2021 Securities Purchase Agreement and Warrants [Abstract]							
Principal amount		$ 4,200		$ 3,400			
Warrants to purchase additional common stock (in shares) | shares				16,666,667			
Warrant exercise price (in dollars per share) | $ / shares				$ 0.18			
Warrants term period				4 years			
Proceeds from, promissory note disbursement	$ 250	$ 750	$ 750				
Original issue discount rate		8.00%	8.00%				
Accrued interest					169		
Interest expense					$ 169		
April 2021 Securities Purchase Agreement and Warrants [Member] | Five Institutions' Notes [Member]							
April 2021 Securities Purchase Agreement and Warrants [Abstract]							
Proceeds from, promissory note disbursement	$ 500						
Number of institutional investors | Investors	5						

Notes Payable, December 2021 Advance on Future Receipts Financing (Details) $ / shares in Units, $ in Thousands	Dec. 22, 2021 USD ($) wk $ / shares shares	Dec. 31, 2021 USD ($) $ / shares	Dec. 31, 2020 USD ($) $ / shares	Dec. 31, 2019 $ / shares
December 2021 Advance on Future Receipts Financing [Abstract]				
Initial liability		$ 57,577	$ 36,745	
Debt discount		$ 5,567	$ 4,324	
Warrant exercise price (in dollars per share) | $ / shares		$ 0.20	$ 0.19	$ 0.11
December 2021 Advances on Future Receipts Financing [Member]				
December 2021 Advance on Future Receipts Financing [Abstract]				
Balance paid	$ 650			
Cash proceeds	758			
Sale of future receipts	$ 1,500			
Non-recourse agreement term | wk	24			
Minimum amount of receipts, payment	$ 59			
Term of minimum amount for receipts | wk	6			
Remaining amount of receipts for payment	$ 98			
Receipts of remaining term | wk	18			
Initial liability	$ 1,500			
Debt discount	$ 90			
Warrants to purchase common stock (in shares) | shares	8,333,334			
Warrant exercise price (in dollars per share) | $ / shares	$ 0.18			
Warrants expiration period		4 years		

Notes Payable, Warrant issuances to Leviston and Five Institutions' in April, May and September 2021 (Details) - USD ($) $ in Thousands	Sep. 03, 2021	May 14, 2021	Apr. 20, 2021	9 Months Ended Sep. 30, 2021	12 Months Ended Dec. 31, 2021
Binomial Pricing Model [Member]					
Embedded Conversion Option Liability [Abstract]					
Principal				$ 2,446	$ 2,446
Fair Value of Conversion Option				4,138	6,255
Leviston Issuances [Member] | Binomial Pricing Model [Member]					
Embedded Conversion Option Liability [Abstract]					
Principal				1,902	1,902
Fair Value of Conversion Option				$ 3,206	$ 5,204
Leviston Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Conversion Price [Member]					
Embedded Conversion Option Liability [Abstract]					
Conversion Price (in dollars per share)				$ 0.18 [1]	$ 0.109 [2]
Leviston Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Interest Rate (annual) [Member]					
Embedded Conversion Option Liability [Abstract]					
Derivative Liability, Measurement Input	[3]			0.0007	0.0016
Leviston Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Volatility (annual) [Member]					
Embedded Conversion Option Liability [Abstract]					
Derivative Liability, Measurement Input	[4]			0.7310	3.0320
Leviston Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Time to Maturity (Years) [Member]					
Embedded Conversion Option Liability [Abstract]					
Time to Maturity (Years)				1 year	4 months 24 days
Five Institution Issuances [Member] | Binomial Pricing Model [Member]					
Embedded Conversion Option Liability [Abstract]					
Principal				$ 544	$ 544
Fair Value of Conversion Option				$ 932	$ 1,051

Five Institution Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Conversion Price [Member]			
Embedded Conversion Option Liability [Abstract]			
Conversion Price (in dollars per share)	$ 0.18 [1]	$ 0.109 [2]	
Five Institution Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Interest Rate (annual) [Member]			
Embedded Conversion Option Liability [Abstract]			
Derivative Liability, Measurement Input [3]	0.0008	0.0026	
Five Institution Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Volatility (annual) [Member]			
Embedded Conversion Option Liability [Abstract]			
Derivative Liability, Measurement Input [4]	0.8010	2.4900	
Five Institution Issuances [Member] | Binomial Pricing Model [Member] | Measurement Input, Time to Maturity (Years) [Member]			
Embedded Conversion Option Liability [Abstract]			
Time to Maturity (Years)	1 year	8 months 12 days	
Leviston Warrants [Member]			
Leviston and Five Institutions Warrants [Abstract]			
Warrants issued (in shares)	1,322,751	3,968,254	3,968,254
Five Institutions Warrants [Member]			
Leviston and Five Institutions Warrants [Abstract]			
Warrants to purchase additional common stock (in shares)	2,777,779		

[1] Based on the terms provided in the warrant agreement to purchase common stock of the Company on the stated issuance dates.

[2] Based on the terms provided in the warrant agreement to purchase common stock of the Company as of December 31, 2021.

[3] Interest rate for U.S. Treasury Bonds, as of each presented period ending date, as published by the U.S. Federal Reserve.Interest rate for U.S. Treasury Bonds, as of each presented period ending date, as published by the U.S. Federal Reserve.

[4] Based on the historical daily volatility of the Company as of each presented period ending date.Based on the historical daily volatility of the Company as of each presented period ending date.

Notes Payable, Interest rates on Leviston and Five Institutions' Notes, Conversion Option, and Loss on Issuance (Details) $ / shares in Units, $ in Thousands	Aug. 31, 2021	Apr. 20, 2021 USD ($)	12 Months Ended Dec. 31, 2021 USD ($) d $ / shares	Dec. 31, 2020 USD ($) $ / shares	Sep. 30, 2021 USD ($)	May 31, 2021 USD ($)	Apr. 30, 2021 USD ($)	Dec. 31, 2019 $ / shares
Conversion Option [Abstract]								
Warrant exercise price (in dollars per share) | $ / shares			$ 0.20	$ 0.19				$ 0.11
Proceeds from, promissory note disbursement			$ 940	$ 13,347				
Leviston Notes [Member]								
Conversion Option [Abstract]								
Default interest rate	15.00%							
Proceeds from, promissory note disbursement		$ 250						
Five Institutions' Notes [Member]								
Conversion Option [Abstract]								
Proceeds from, issuance of one-time aggregate amount			$ 56					
Percentage of outstanding principal			5.00%					
Five Institutions' Notes [Member] | Minimum [Member]								
Conversion Option [Abstract]								
Conversion price (in dollars per share) | $ / shares			$ 0.01					
Leviston Disbursements and Five Institutions' Notes [Member]								
Conversion Option [Abstract]								
Promissory note disbursement, interest rate			5.00%					
Default interest rate			15.00%					
Common stock conversion volume-weighted price percentage			75.00%					
Number of trading days | d			10					
Fair value of convertible notes					$ 1,400	$ 1,400	$ 1,400	
Loss on issuance					$ 1,100	$ 1,100	$ 1,400	
Promissory note maturity term			12 months					
Warrant exercise price (in dollars per share) | $ / shares			$ 0.18					
Common stock conversion price percentage			90.00%					

Notes Payable, Convertible Promissory Notes Payable (HealthTronics), in Default (Details) - USD ($) $ / shares in Units, $ in Thousands	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Aug. 06, 2020
Convertible Notes Payable Related Parties [Abstract]			
Accrued interest, related parties	$ 289	$ 77	
Health Tronics [Member] | Convertible Note [Member]			
Convertible Notes Payable Related Parties [Abstract]			
Principal amount			$ 1,400
Maturity date	Aug. 06, 2021		
Accrued interest rate			2.00%
Interest rate			12.00%
Accrued interest, related parties	$ 241	$ 66	
Common stock conversion price (in dollars per share)			$ 0.10

Notes Payable, Convertible Promissory Notes Payable (Stolarski), in Default (Details) - USD ($) $ / shares in Units, $ in Thousands	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Aug. 06, 2020
Convertible Note [Abstract]			
Accrued interest, related parties	$ 289	$ 77	
A. Michael Stolarski [Member] | Convertible Note [Member]			
Convertible Note [Abstract]			
Principal amount			$ 223
Maturity date	Aug. 06, 2021		
Accrued interest rate			2.00%
Interest rate			12.00%
Accrued interest, related parties	$ 41	$ 11	
Common stock conversion price (in dollars per share)			$ 0.10

Notes Payable, September 2021 Advances on Future Receipts Financing (Details) $ / shares in Units, $ in Thousands	Sep. 27, 2021 USD ($) Payment wk $ / shares shares	Dec. 31, 2021 USD ($) $ / shares	Dec. 31, 2020 USD ($) $ / shares	Dec. 31, 2019 $ / shares
Advances on Future Receipts Financing [Abstract]				
Initial liability		$ 57,577	$ 36,745	
Debt discount		$ 5,567	$ 4,324	
Warrant exercise price (in dollars per share) | $ / shares		$ 0.20	$ 0.19	$ 0.11
September 2021 Advances on Future Receipts Financing [Member]				
Advances on Future Receipts Financing [Abstract]				
Cash proceeds	$ 703			
Sale of future receipts	$ 1,000			
Non-recourse agreement term | wk	24			
Minimum amount of receipts, payment	$ 59			
Number of payments occurring at closing | Payment	4			
Initial liability	$ 763			
Debt discount	$ 60			
Warrants to purchase common stock (in shares) | shares	5,555,556			
Warrant exercise price (in dollars per share) | $ / shares	$ 0.18			

Notes Payable, SBA Loans (Details) - USD ($) $ in Thousands	3 Months Ended	12 Months Ended			
	Sep. 30, 2021	Dec. 31, 2021	Dec. 31, 2020	Aug. 27, 2021	Feb. 20, 2021
SBA Loans [Abstract]					
Gain on extinguishment of debt		$ 204	$ (565)		
SBA Loan #1 [Member]					
SBA Loans [Abstract]					
Forgiveness of loan, principal amount				$ 454	
Forgiveness of loan, interest amount				$ 6	
Gain on extinguishment of debt	$ 460				
Debt maturity date		May 28, 2022			
Interest rate			1.00%		
SBA Loan #2 [Member]					
SBA Loans [Abstract]					
Proceeds from PPP loan					$ 1,030
Debt maturity date		Feb. 20, 2026			
Interest rate		1.00%			1.00%
Frequency of payment		monthly			
Term of covered period		168 days			
Term of deferment period		10 months			
SBA loan classified as current		$ 158			
SBA loan classified as non-current		$ 875			

Common Stock Purchase Warrants (Details) - $ / shares	Feb. 03, 2021	12 Months Ended		
		Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Warrants [Abstract]				
Outstanding, beginning (in shares)		190,356,736	9,474,091	
Issuances (in shares)		25,925,928	189,182,645	
Exercised (in shares)		(11,400,000)	(8,200,000)	
Forfeited or expired (in shares)		0	(100,000)	
Outstanding, ending (in shares)		204,882,664	190,356,736	9,474,091
Weighted Average Exercise Price per share [Abstract]				
Outstanding, beginning (in dollars per share)		$ 0.19	$ 0.11	
Issuances (in dollars per share)		0.18	0.19	
Exercised (in dollars per share)		0.01	0.10	
Forfeited or expired (in dollars per share)		0	0.20	
Outstanding, ending (in dollars per share)		$ 0.20	$ 0.19	$ 0.11
Weighted Average Remaining Contractual Life (Years) [Abstract]				
Weighted Average Remaining Contractual Life (years)		2 years 6 months 14 days	3 years 5 months 4 days	5 years 10 days
LGH Warrant [Member]				
Warrants [Abstract]				
Exercised (in shares)	(11,400,000)			
Outstanding, ending (in shares)	23,600,000			
Weighted Average Remaining Contractual Life (Years) [Abstract]				
Issued (in shares)	10,925,000			

Fair Value Measurements, Liabilities Measured at Fair Value on Recurring Basis (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Fair Value, Measurement with Unobservable Inputs Reconciliation, Recurring Basis, Liability, Transfers, Net [Abstract]		
Transfer from level 1 to level 2	$ 0	$ 0
Transfer to level 1 from level 2	0	0
Transfer to level 3	0	0
Transfer from level 3	0	0
Recurring [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	15,869	8,855
Recurring [Member] | Warrant Liability [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	9,614	8,855
Recurring [Member] | Embedded Conversion Option [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	6,255	0
Recurring [Member] | Quoted Prices in Active Markets (Level 1) [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	0	0
Recurring [Member] | Quoted Prices in Active Markets (Level 1) [Member] | Warrant Liability [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	0	0
Recurring [Member] | Quoted Prices in Active Markets (Level 1) [Member] | Embedded Conversion Option [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	0	0
Recurring [Member] | Significant Other Observable Inputs (Level 2) [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	0	0
Recurring [Member] | Significant Other Observable Inputs (Level 2) [Member] | Warrant Liability [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	0	0
Recurring [Member] | Significant Other Observable Inputs (Level 2) [Member] | Embedded Conversion Option [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	0	0
Recurring [Member] | Significant Unobservable Inputs (Level 3) [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		

Liabilities at fair value	15,869	8,855
Recurring [Member] | Significant Unobservable Inputs (Level 3) [Member] | Warrant Liability [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	9,614	8,855
Recurring [Member] | Significant Unobservable Inputs (Level 3) [Member] | Embedded Conversion Option [Member]		
Financial Liabilities Fair Value Disclosure [Abstract]		
Liabilities at fair value	$ 6,255	$ 0

Fair Value Measurements, Warrants Fair Value, Outstanding and Valuation Model (Details)	12 Months Ended		
	Dec. 31, 2021 USD ($) $ / shares shares	Dec. 31, 2020 USD ($) $ / shares shares	Dec. 31, 2019 USD ($) $ / shares shares
Warrant Outstanding and Fair Value [Abstract]			
Warrants outstanding (in shares) | shares	62,617,188	48,091,160	0
Cashless exercise of LGH Warrants (in shares) | shares	(11,400,000)	(8,200,000)	
Gain on remeasurement of warrant liability (in shares) | shares	0	0	
Fair value per share (in dollars per share) | $ / shares	$ 0.15	$ 0.18	$ 0
Cashless exercise of LGH Warrants. Fair value per share (in dollars per share) | $ / shares	$ 0.18		
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	$ 9,614,134	$ 8,855,379	$ 0
Cashless exercise of LGH Warrants, Fair Value	(2,030,052)		
Gain on remeasurement of warrant liability	$ 506,545	$ 3,192,620	
Measurement Input, Weighted Average Expected Life in Years [Member]			
Black Scholes Option Pricing Model [Abstract]			
Weighted average expected life in years (Years)	4 years 8 months 1 day	7 years	
Measurement Input, Weighted Average Volatility (annual) [Member]			
Black Scholes Option Pricing Model [Abstract]			
Warrants measurement input	1.16	1.21	
Measurement Input, Weighted Average Risk Free Interest Rate [Member]			
Black Scholes Option Pricing Model [Abstract]			
Warrants measurement input	0.012	0.005	
Measurement Input, Expected Dividend Yield [Member]			
Black Scholes Option Pricing Model [Abstract]			
Warrants measurement input	0.0000	0.0000	
Warrant Classified [Member]			
Warrant Outstanding and Fair Value [Abstract]			
Warrants outstanding (in shares) | shares	25,926,028	112,210,902	
Fair value per share (in dollars per share) | $ / shares	$ 0.10	$ 0.11	
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	$ 2,282,262	$ 11,955,454	
Warrants Reclassified [Member]			
Warrant Outstanding and Fair Value [Abstract]			
Warrants outstanding (in shares) | shares		(64,119,742)	
Fair value per share (in dollars per share) | $ / shares		$ 0.10	
Fair Value, Warrant Liability [Abstract]			

Warrant Liability, Fair Value		$ (6,292,695)	
Level 3 [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	15,869,000	8,855,000	0
Transfer of convertible feature	4,139,000		
Cashless exercise of LGH Warrants, Fair Value	(2,030,000)		
Gain on remeasurement of warrant liability	2,623,000	3,193,000	
Level 3 [Member] | Warrant Classified [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	2,282,000	11,955,000	
Level 3 [Member] | Warrants Reclassified [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value		(6,293,000)	
Level 3 [Member] | Warrant Liability [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	9,614,000	8,855,000	0
Transfer of convertible feature	0		
Cashless exercise of LGH Warrants, Fair Value	(2,030,000)		
Gain on remeasurement of warrant liability	507,000	3,193,000	
Level 3 [Member] | Warrant Liability [Member] | Warrant Classified [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	2,282,000	11,955,000	
Level 3 [Member] | Warrant Liability [Member] | Warrants Reclassified [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value		(6,293,000)	
Level 3 [Member] | Embedded Conversion Option [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	6,255,000	0	$ 0
Transfer of convertible feature	4,139,000		
Cashless exercise of LGH Warrants, Fair Value	0		
Gain on remeasurement of warrant liability	2,116,000	0	
Level 3 [Member] | Embedded Conversion Option [Member] | Warrant Classified [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value	$ 0	0	
Level 3 [Member] | Embedded Conversion Option [Member] | Warrants Reclassified [Member]			
Fair Value, Warrant Liability [Abstract]			
Warrant Liability, Fair Value		$ 0	

Leases, ROU Assets and Lease Liability (Details) - USD ($) $ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Operating Leases [Abstract]		
Right of use assets	$ 725	$ 725
Operating Lease, Right-of-Use Asset, Statement of Financial Position [Extensible Enumeration]	Right of use assets, net	Right of use assets, net
Less: Accumulated amortization	$ (574)	$ (339)
Right of use assets, net	151	386
Lease Liabilities	$ 157	$ 415
Operating Lease, Liability, Statement of Financial Position [Extensible Enumeration]	Lease Liabilities	Lease Liabilities
Less: current portion	$ (83)	$ (257)
Operating Lease, Liability, Current, Statement of Financial Position [Extensible Enumeration]	Less: current portion	Less: current portion
Lease liabilities	$ 74	$ 158
Operating Lease, Liability, Noncurrent, Statement of Financial Position [Extensible Enumeration]	Lease liabilities	Lease liabilities
Financing Leases [Abstract]		
Right of use assets	$ 626	$ 644
Finance Lease, Right-of-Use Asset, Statement of Financial Position [Extensible Enumeration]	Right of use assets, net	Right of use assets, net
Less: Accumulated amortization	$ (433)	$ (235)
Right of use assets, net	193	409
Lease Liability	$ 229	$ 427
Finance Lease, Liability, Statement of Financial Position [Extensible Enumeration]	Lease Liabilities	Lease Liabilities
Less: current portion	$ (185)	$ (194)
Finance Lease, Liability, Current, Statement of Financial Position [Extensible Enumeration]	Less: current portion	Less: current portion
Lease liabilities	$ 44	$ 233
Finance Lease, Liability, Noncurrent, Statement of Financial Position [Extensible Enumeration]	Lease liabilities	Lease liabilities
Total [Abstract]		
Right of use assets	$ 1,351	$ 1,369
Less: Accumulated amortization	(1,007)	(574)
Right of use assets, net	344	795
Lease Liabilities	386	842
Less: current portion	(268)	(451)
Lease liabilities	$ 118	$ 391

Leases, Lease Costs (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Finance lease costs [Abstract]		
Amortization of right-of-use assets	$ 217	$ 94
Interest on lease liabilities	41	33
Operating lease costs	350	118
Total lease costs	$ 608	$ 245

Leases, Cash Paid for Amounts Included in Measurement of Lease Liabilities (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Cash paid for amounts included in measurement of lease liabilities [Abstract]		
Operating cash flows from finance leases	$ (234)	$ (103)
Operating cash flows from operating leases	$ (350)	$ (118)

Leases, Operating Leases, Remaining Lease Terms (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Maturities of Operating Lease Liability [Abstract]		
2022 (remainder of year)	$ 96	
2023	68	
2024	11	
Total lease payments	175	
Less: Present value adjustment	(18)	
Lease liability	$ 157	$ 415
Weighted average remaining lease term, operating lease	1 year 1 month 6 days	
Weighted average discount rate, operating lease	12.00%	
Rent expense	$ 362	$ 297

Leases, Finance Lease, Remaining Lease Terms (Details) - USD ($) $ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Maturities of Finance Lease Liability [Abstract]		
2022 (remainder of year)	$ 200	
2023	18	
Total lease payments	218	
Present value adjustment	11	
Lease liability	$ 229	$ 427
Weighted average remaining lease term, finance lease	1 year	
Weighted average discount rate, finance lease	13.20%	

Common Stock (Details) - $ / shares	Jul. 23, 2020	Dec. 31, 2021	Dec. 31, 2020	Dec. 30, 2020	Jun. 30, 2020
Common Stock [Abstract]					
Common stock, shares authorized (in shares)	600,000,000	800,000,000	800,000,000	800,000,000	355,000,000
Common stock, par value (in dollars per share)	$ 0.001	$ 0.001	$ 0.001		
Minimum [Member]					
Common Stock [Abstract]					
Reverse stock splits (in shares)	10				
Maximum [Member]					
Common Stock [Abstract]					
Reverse stock splits (in shares)	50				

Preferred Stock (Details) - USD ($) $ / shares in Units, $ in Thousands	12 Months Ended				
	Sep. 20, 2020	Dec. 31, 2021	Dec. 31, 2020	May 14, 2020	Feb. 06, 2020
Preferred Stock [Abstract]					
Preferred stock, shares authorized (in shares)		5,000,000	5,000,000		
Preferred stock, shares issued (in shares)		0	0		
Preferred stock, par value (in dollars per share)		$ 0.001	$ 0.001		
Aggregate total purchase price		$ 0	$ 0		
Anti-dilutive equity securities (in shares)		290,332,000	232,861,000		
Preferred Stock Conversion [Member]					
Preferred Stock [Abstract]					
Anti-dilutive equity securities (in shares)		17,500,000			
Series C Preferred Stock [Member]					
Preferred Stock [Abstract]					
Preferred stock, shares authorized (in shares)		90	90		90
Shares conversion price (in dollars per share)					$ 0.14
Series C Preferred Stock [Member] | Private Placement [Member]					
Preferred Stock [Abstract]					
Preferred stock, shares issued (in shares)		90			
Preferred stock, par value (in dollars per share)					0.001
Preferred stock, stated value (in dollars per share)					$ 25,000
Aggregate total purchase price					$ 2,300
Series D Preferred Stock [Member]					
Preferred Stock [Abstract]					
Preferred stock, shares authorized (in shares)		8	8	8	
Shares conversion price (in dollars per share)				$ 0.14	
Series D Preferred Stock [Member] | Private Placement [Member]					
Preferred Stock [Abstract]					
Preferred stock, shares issued (in shares)		8			
Preferred stock, par value (in dollars per share)				0.001	
Preferred stock, stated value (in dollars per share)				$ 25,000	
Aggregate total purchase price				$ 200	
Series C and D Preferred Stock [Member]					
Preferred Stock [Abstract]					
Convertible preferred stock converted to common stock (in shares)	17,499,958				

Related party transactions (Details)	Apr. 01, 2022 USD ($) Systems	Jul. 01, 2021 USD ($)	1 Months Ended Mar. 31, 2021 USD ($)	12 Months Ended Dec. 31, 2021 USD ($)	Dec. 31, 2020 USD ($)	Oct. 27, 2021 USD ($)	Dec. 31, 2019 USD ($)	Feb. 13, 2018
Related Party Transaction Disclosures [Abstract]								
Contract liabilities				$ 341,000	$ 69,000		$ 128,000	
Related party accounts payable				127,000				
Proceeds from related party deposits				175,000	23,000			
A. Michael Stolarski [Member]								
Related Party Transaction Disclosures [Abstract]								
Revenue from related party				32,000	45,000			
Contract liabilities				38,000	$ 70,000			
Deposits for future purchase of medical equipment				$ 125,000				
A. Michael Stolarski [Member] | April 2022 Advances from Directors [Member] | Subsequent Event [Member]								
Related Party Transaction Disclosures [Abstract]								
Advances from related parties	$ 250,000							
A. Michael Stolarski [Member] | October 2021 Advances from Directors [Member]								
Related Party Transaction Disclosures [Abstract]								
Advances from related parties						$ 25,000		
Proceeds from related party deposits			$ 125,000					
Principal amount						$ 150,000		
Maturity date				Jun. 30, 2022				
Interest rate						15.00%		
A. Michael Stolarski [Member] | UltraMIST Devices [Member] | April 2022 Advances from Directors [Member] | Subsequent Event [Member]								

Related Party Transaction Disclosures [Abstract]			
Number of systems used as collateral | Systems	18		
Repurchase of collateral amount	$ 256,000		
PSWC [Member]			
Related Party Transaction Disclosures [Abstract]			
Purchase price multiplier in reference to EBITDA			5.5
Purchase from related party		$ 127,000	
Monthly rent of equipment		$ 3,600	

Stock-based Compensation, Stock Inventive Plan (Details) - Stock Incentive Plan [Member] - USD ($)	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Share-based Compensation Arrangement by Share-based Payment Award, Options, Additional Disclosures [Abstract]			
Non-statutory options expiration period	10 years		
Common stock shares reserved (in shares)	35,000,000	35,000,000	
Options [Roll Forward]			
Outstanding (in shares)	31,938,385		34,303,385
Granted (in shares)	0	100,000	
Exercised (in shares)	0	(325,000)	
Forfeited or expired (in shares)	(179,000)	(2,140,000)	
Outstanding (in shares)	31,759,385	31,938,385	
Vested and exercisable (in shares)	31,409,385		
Weighted Average Exercise Price [Roll Forward]			
Outstanding (in dollars per share)	$ 0.26		$ 0.28
Granted (in dollars per share)	0	$ 0.26	
Exercised (in dollars per share)	0	0.15	
Forfeited or expired (in dollars per share)	0.18	0.71	
Outstanding (in dollars per share)	0.26	$ 0.26	
Vested and exercisable (in dollars per share)	$ 0.26		
Weighted average remaining contractual term for outstanding exercisable stock options	4 years 11 months 1 day	5 years 11 months 8 days	6 years 7 months 13 days
Weighted average remaining contractual term for exercisable stock options	4 years 11 months 1 day		
Aggregate intrinsic value for outstanding options	$ 1,056,236	$ 1,372,116	$ 981,088
Aggregate intrinsic value for vested and exercisable options	$ 1,056,236		
Shares available for grant (in shares)	3,240,615		
Maximum [Member]			
Share-based Compensation Arrangement by Share-based Payment Award, Options, Additional Disclosures [Abstract]			
Non-statutory options vesting period	3 years		

Stock-based Compensation, Weighted Average Assumptions (Details) - USD ($)	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Weighted average assumptions [Abstract]			
Weighted average expected life in years	2 years 6 months 14 days	3 years 5 months 4 days	5 years 10 days
Stock Option [Member]			
Weighted average assumptions [Abstract]			
Weighted average expected life in years		5 years	
Weighted average volatility		124.00%	
Weighted average risk-free interest rate		1.60%	
Expected dividend yield		0.00%	
Compensation cost related to options granted	$ 0	$ 22,000	
Unamortized compensation cost related to options granted	$ 0	$ 0	

Joint ventures (Details) - USD ($)	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Dec. 13, 2019
Joint Venture Agreements [Abstract]			
Partnership fee received	$ 0	$ 600,000	
JV Agreement [Member]			
Joint Venture Agreements [Abstract]			
Partnership fee			$ 600,000
Partnership fee received		$ 600,000	

Income taxes, Components of Income Tax Provision (Benefit) from Continuing Operations (Details) - USD ($) $ in Thousands	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Components of Net Loss Before Income Taxes [Abstract]		
Domestic	$ (27,208)	$ (30,945)
Foreign	(23)	8
Net Loss before Income Taxes	(27,231)	(30,937)
Current [Abstract]		
Federal	0	0
State	28	0
Foreign	0	0
Total	28	0
Deferred [Abstract]		
Federal	(5,038)	(5,420)
State	(869)	(964)
Foreign	4	1
Change in valuation allowance	5,903	6,383
Total	$ 28	$ 0

Income taxes, Income Tax Provision (Benefit) (Details) - USD ($)	12 Months Ended	
	Dec. 31, 2021	Dec. 31, 2020
Income taxes [Abstract]		
Undistributed earnings of foreign subsidiaries	$ 0	$ 0
Percentage of federal statutory income tax rate	21.00%	21.00%
Tax expense (benefit) at statutory rate	$ (5,718,000)	$ (6,498,000)
Increase (reduction) in income taxes resulting from [Abstract]		
State income taxes (benefits), net of federal benefit	(837,000)	(913,000)
Non-deductible gain on warrant adjustment valuation	417,000	670,000
Income from foreign subsidiaries	0	2,000
Change in valuation allowance	5,903,000	6,383,000
Registration penalties	354,000	0
Other	(91,000)	356,000
Income tax expense (benefit)	$ 28,000	$ 0

Income taxes, Deferred Tax Assets (Details) - USD ($)	12 Months Ended				
	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
Deferred tax assets [Abstract]					
Net operating loss carryforwards	$ 33,238,000	$ 28,048,000			
Net operating loss carryforwards - foreign	23,000	19,000			
Excess of tax basis over book value of property and equipment	14,000	8,000			
Excess of tax basis over book value of intangible assets	1,632,000	1,811,000			
Stock-based compensation	1,613,000	1,613,000			
Accrued employee compensation	698,000	427,000			
Capitalized equity costs	49,000	49,000			
Net change in reserve accounts	898,000	287,000			
Gross deferred tax assets	38,165,000	32,262,000			
Valuation allowance	(38,165,000)	(32,262,000)			
Net deferred tax asset	0	0			
Income Tax Penalties and Interest Expense [Abstract]					
Income tax penalties	0	0			
Interest on income taxes	$ 0	0			
Earliest Tax Year [Member]					
Operating Loss Carryforwards [Abstract]					
Operating loss carryforwards, expiry date	Dec. 31, 2024				
Latest Tax Year [Member]					
Operating Loss Carryforwards [Abstract]					
Operating loss carryforwards, expiry date	Dec. 31, 2025				
Domestic [Member]					
Operating Loss Carryforwards [Abstract]					
Net operating loss carryforwards					$ 77,900,000
Operating loss carryforwards limited with no expiration	$ 56,500,000	56,500,000	$ 56,500,000	$ 56,500,000	
Foreign [Member]					
Operating Loss Carryforwards [Abstract]					
Net operating loss carryforwards			100,000		
State and Local Jurisdiction [Member]					
Operating Loss Carryforwards [Abstract]					
Net operating loss carryforwards					$ 77,900,000

Operating loss carryforwards limited with no expiration	$ 56,500,000	$ 56,500,000	$ 56,500,000	$ 56,500,000

Subsequent Events, Warrant Exercises (Details) - USD ($) $ in Thousands		12 Months Ended	
	May 03, 2022	Dec. 31, 2021	Dec. 31, 2020
Subsequent Event [Abstract]			
Proceeds from warrant exercises		$ 0	$ 10
Exercised (in shares)		(11,400,000)	(8,200,000)
Subsequent Event [Member] | Warrant Exercises [Member]			
Subsequent Event [Abstract]			
Proceeds from warrant exercises	$ 100		
Exercised (in shares)	(15,900,000)		
Warrants issued (in shares)	14,900,000		

Subsequent Events, Second Amendment to Note and Warrant Purchase and Security Agreement (Details) - USD ($) $ / shares in Units, $ in Millions	May 03, 2022	Feb. 25, 2022	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Subsequent Event [Abstract]					
Issuance of warrants (in shares)			204,882,664	190,356,736	9,474,091
Warrant exercise price (in dollars per share)			$ 0.20	$ 0.19	$ 0.11
Second Amendment to Note and Warrant Purchase and Security Agreement [Member]					
Subsequent Event [Abstract]					
Warrants and Rights Outstanding, Term			10 years		
Subsequent Event [Member] | Second Amendment to Note and Warrant Purchase and Security Agreement [Member]					
Subsequent Event [Abstract]					
Proceeds from issuance of debt	$ 3.0				
Principal amount	$ 3.0				
Issuance of advisor shares (in shares)	20,700,000				
Issuance of warrants (in shares)	15,500,000				
Warrant exercise price (in dollars per share)		$ 0.18			