UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2020

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: 001-36445

NanoVibronix, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**01-0801232**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
525 Executive Blvd. Elmsford, New York	**10523**
(Address of principal executive office)	(Zip Code)

Registrant's telephone number, including area code: **(914) 233-3004**

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	NOAV	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

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

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 [X]

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		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 the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

The aggregate market value of our common stock held by non-affiliates as of June 30, 2020, was approximately $9,447,579.

The number of shares outstanding of the registrant's Common Stock as of March 23, 2021 was 24,109,635 shares.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Form 10-K, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders. Such proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

PART I

ITEM 1. BUSINESS

Cautionary Note Regarding Forward-Looking Statements; Risk Factor Summary

This Annual Report on Form 10-K contains "forward-looking statements," which include information relating to future events, future financial performance, financial projections, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to a number of risks, and uncertainties and assumptions that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. These risk are more fully described in the "Risk Factors" section of this Annual Report on Form 10-K. The following is a summary of such risks:

- Our history of losses and expectation of continued losses.
- The risk that we may not obtain the requisite votes at our special meeting to ratify an increase in the number of authorized shares of common stock and the related issuance of such shares.
- The geographic, social and economic impact of COVID-19 on the Company's business operations.
- Our ability to raise funding for, and the timing of, clinical studies and eventual U.S. Food and Drug Administration approval of our product candidates.
- Regulatory actions that could adversely affect the price of or demand for our approved products.
- Market acceptance of existing and new products.
- Favorable or unfavorable decisions about our products from government regulators, insurance companies or other third-party payers.
- Risks of product liability claims and the availability of insurance.
- Our ability to successfully develop and commercialize our products.
- Our ability to generate internal growth.
- Risks related to computer system failures and cyber-attacks.
- Our ability to obtain regulatory approval in foreign jurisdictions.
- Uncertainty regarding the success of our clinical trials for our products in development.
- Risks related to our operations in Israel, including political, economic and military instability.
- The price of our securities is volatile with limited trading volume
- Our ability to comply with the continued listing requirements of the NASDAQ capital market.
- Our ability to maintain effective internal control over financial reporting and to remedy identified material weaknesses.
- We are a "smaller reporting company" and have reduced disclosure obligations that may make our stock less attractive to investors.
- Our intellectual property portfolio and our ability to protect our intellectual property rights.
- Our ability to recruit and retain qualified regulatory and research and development personnel.
- Unforeseen changes in healthcare reimbursement for any of our approved products.
- The adoption of health policy changes and health care reform.
- Lack of financial resources to adequately support our operations.
- Difficulties in maintaining commercial scale manufacturing capacity and capability.
- Our ability to generate internal growth.
- Changes in our relationship with key collaborators.
- Changes in the market valuation or earnings of our competitors or companies viewed as similar to us.
- Our failure to comply with regulatory guidelines.
- Uncertainty in industry demand and patient wellness behavior.
- General economic conditions and market conditions in the medical device industry.
- Risks related to our operations in Israel.
- Future sales of large blocks of our common stock, which may adversely impact our stock price.
- Depth of the trading market in our common stock.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see "Item 1A. Risk Factors" for additional risks which could adversely impact our business and financial performance. Moreover, new risks regularly emerge, and it is not possible for us to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Form 10-K are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Unless the context otherwise indicates or requires, the terms “we,” “our,” “us,” “NanoVibronix,” and the “Company,” as used in this Annual Report on Form 10-K, refer to NanoVibronix, Inc. and its subsidiaries as a combined entity, except where otherwise stated or where it is clear that the terms mean only NanoVibronix, Inc. exclusive of its subsidiaries.

Overview

We were organized as a Delaware corporation in October 2003. Through our wholly-owned subsidiary, NanoVibronix Ltd., a private company incorporated under the laws of the State of Israel, we focus on noninvasive biological response-activating devices that target biofilm prevention, pain therapy , and wound healing and can be administered at home, without the assistance of medical professionals. Our primary products, which are in various stages of clinical and market development, currently consist of:

- UroShield™, an ultrasound-based product that is designed to prevent bacterial colonization and biofilm in urinary catheters, increase antibiotic efficacy and decrease pain and discomfort associated with urinary catheter use;

- PainShield™, a patch-based therapeutic ultrasound technology to treat pain, muscle spasm and joint contractures by delivering a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area; and

- WoundShield™, a patch-based therapeutic ultrasound device intended to facilitate tissue regeneration and wound healing by using ultrasound to increase local capillary perfusion and tissue oxygenation.

Each of our UroShield, PainShield, and WoundShield products employs a small, disposable transducer that transmits low frequency, low intensity ultrasound acoustic waves that seek to repair and regenerate tissue, musculoskeletal and vascular structures, and decrease biofilm formation on urinary catheters and associated urinary tract infections. Through their size, effectiveness and ease of use, these products are intended to eliminate the need for technicians and medical personnel to manually administer ultrasound treatment through large transducers, thereby promoting patient independence and enabling more cost-effective home-based care.

PainShield is currently cleared for marketing in the United States by the U.S. Food and Drug Administration. In September 2020, the U.S. Food and Drug Administration exercised its Enforcement Discretion to allow distribution of the UroShield device in the U.S. during the COVID-19 pandemic. While the permitted use is currently temporary, it does permit the import of the UroShield to the U.S. during the COVID-19 pandemic. All three of our products have CE Mark approval in the European Union, and a certificate allowing us to sell PainShield, UroShield and WoundShield in Israel. We are able to sell PainShield, UroShield and WoundShield in India and Ecuador based on our CE Mark. We have consummated sales of PainShield and UroShield in the relevant markets, although to date sales have been minimal; WoundShield has not generated significant revenue to date. Outside of the United States we generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

In the United States, PainShield and UroShield requires a prescription from a licensed healthcare practitioner. If U.S. Food and Drug Administration clearance is obtained, we anticipate that WoundShield will require a prescription from a licensed healthcare practitioner in the United States. UroShield has been approved through the U.S. Food and Drug Administration under Enforcement Discretion for the duration of the Covid-19 health emergency and is intended to be sold directly to health care facilities and therefore will not require a prescription for these venues. However, in other countries in which we sell PainShield, UroShield, and WoundShield, such products are eligible for sale without a prescription.

In addition to the need to obtain regulatory approvals, we anticipate that sales volumes and prices of our UroShield, PainShield, and WoundShield products will depend in large part on the availability of insurance coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid in the United States, private insurance plans and workers' compensation plans. We do not currently have reimbursement codes for use of WoundShield in any of the markets in which we have regulatory authority to sell WoundShield. Of the markets in which we have regulatory authority to sell PainShield, prior to January 2020, we only had reimbursement codes in the United States (i.e., CPT codes) for clinical use only. Effective as of January 2020, the U.S. Centers for Medicare and Medicaid Services (CMS) approved our PainShield™ for reimbursement for Medicare beneficiaries on a national basis. We were notified on March 30, 2020 that our Medicare Enrollment Application was approved, and we are now an approved Medicare Supplier for Durable Medical Equipment, or DME, through the National Supplier Clearinghouse, Palmetto-GBA as well as Noridian Administrative Services, LLC, the two Medicare Administrative Contractors that handle DME reimbursement nationwide. PainShield is currently available for Medicare reimbursement on a national level under new HCPCS (Healthcare Common Procedure Coding System) code K1004. With respect to UroShield, which may be used in a clinical and home setting, we do not currently have reimbursement codes in any of the markets in which we have regulatory authority to sell UroShield. We are seeking reimbursement codes for use of our products in the markets in which we have regulatory authority, including the United States, to sell such products. Our current ongoing research and planned research may facilitate our ability to obtain reimbursement codes and there is no guarantee that we will be successful in obtaining such codes quickly, or at all. We have engaged two reimbursement experts, Redemption Revenue Cycle Solutions, LLC, and McGuire Woods, to help facilitate insurance reimbursement.

We have completed six separate clinical studies with UroShield that together evaluated approximately 194 patients with urinary catheters. In patients where the UroShield product was used there were no serious adverse events reported, while a variety of clinical beneficial observations were seen including: catheter biofilm reduction, reduction in catheter associated pain, reduction in urinary tract infections, and a significant decrease in bacteriuria rates. We completed a double blind clinical trial for UroShield in the United States in October 2018. The results of the study, entitled "The Effect of Surface Acoustic Waves on Bacterial Load and Preventing Catheter-Associated Urinary Tract Infections (CAUTI) in Long Term Indwelling Catheters," were published in the December 2018 issue of Medical & Surgical Urology, a peer-reviewed journal in the field of urology. In the study, 55 patients in a skilled nursing facility chain treated with long term indwelling catheters were evaluated. There was a significant difference between the treated group and the placebo group in the number of colony forming units ("CFU") present upon evaluation, as well as on the number of treated urinary tract infections ("UTI"), and the effect lasted beyond the time of active treatment. The study concluded that the UroShield™ device was shown to be effective in significantly reducing the number of CFUs in patients with indwelling catheters. The study also concluded that the UroShield™ device was shown to be effective in reducing the number of treated UTIs in this patient population, and surface acoustic waves in the form of the UroShield™ device is an effective tool in the prevention of catheter-associated UTI and while further evaluation is encouraged, can be safely utilized with a high likelihood of success. In July 2017, we engaged Idonea Solutions, Inc., an FDA consultant, to assist in our efforts to obtain clearance under the FDA's Enforcement Discretion, and obtain 510(K) clearance which is still ongoing. If we are successful, we intend to pursue obtaining reimbursement codes and to target completion of partnerships with leading catheter product companies for sales and marketing efforts in the United States. The Company has entered into recent distribution partnerships for UroShield in the United States, U.K., Switzerland, Israel, India, and New Zealand.

In addition, we continue to expand our clinical development and marketing efforts in North America with respect to PainShield. In February 2018, we completed a clinical trial to evaluate the effect of PainShield in patients with trigeminal neuralgia. The double blinded, crossover trial was conducted across the United States and included 59 patients with a diagnosis of unilateral trigeminal neuralgia. Among the 59 patients, 30 were in the active treatment group and 29 were in the control group. The values which were assessed include Visual Analog Scale ("VAS") pain score, both baseline prior to trial and VAS pain score at the end of the study. The study also assessed breakthrough medications per week at the start of the trial and breakthrough medications per week at the end of the trial, with a particular focus on the use of opioids. Breakthrough medications are used for chronic pain directly related to the pre-existing trigeminal neuralgia condition. There was a significant difference in the outcomes of the two groups relative to pain, quality of life, and breakthrough medications taken, which was directly correlated to pain experienced during treatment. Specifically, the control group saw an improvement in baseline scores of 2.3% versus the treatment group, which saw a 55.2% improvement in baseline scores. Additionally, the control group saw a reduction in breakthrough pain medication of 1.5% versus the treatment group, which saw a 46.4% reduction in breakthrough pain medication.

In 2019, the Company has completed a study which was intended to assess the PainShield's ability to effectively treat Lateral Epicondylitis (Tennis Elbow). This is a double blinded, randomized control trial. The study has been completed and awaiting submission to an appropriate journal. The interim results were reported as follows:

- 70% of patients using PainShield experienced complete resolution or significant improvement in symptoms without the use of opioids; and
- PainShield had no adverse events or complications and was deemed both safe and effective.

The Company has entered into distribution partnerships for PainShield in the United States, Israel, India, Italy, United Kingdom, and Switzerland.

WoundShield has been evaluated in two published clinical studies done to-date that suggest improved localized blood flow and oxygenation, and improved topical oxygen saturation (Morykwas M, "Oxygen Therapy with Surface Acoustic Waveform Sonication," European Wound Management Association 2011; Covington S, "Ultrasound-Mediated Oxygen Delivery to Lower Extremity Wounds," Wounds 2012; 24(8)). We supplied devices for these studies but had no further involvement with them. We are pursuing licensing opportunities to develop commercial markets for the WoundShield product.

Recent Developments

Effective as of January 2020, the U.S. CMS approved our PainShield™ for reimbursement for Medicare beneficiaries on a national basis. We were notified on March 30, 2020 that our Medicare Enrollment Application was approved, and we are now an approved Medicare Supplier for DME through the National Supplier Clearinghouse, Palmetto-GBA as well as Noridian Administrative Services, LLC, the two Medicare Administrative Contractors that handle DME reimbursement nationwide. PainShield is currently available for Medicare reimbursement on a national level under new HCPCS (Healthcare Common Procedure Coding System) code K1004, as discussed above.

In March 2020, we signed a license agreement with Sanuwave Health, Inc. ("Sanuwave") for the manufacture and delivery of our WoundShield technology. Under the terms of the agreement, we will receive warrants to purchase 127,000 shares of Sanuwave stock, a $250,000 milestone payment based on receipt of U.S. Food and Drug Administration approval, and 10% royalty on Sanuwave's gross revenues from sales or rentals of WoundShield. In return, Sanuwave has received the worldwide, exclusive rights to our WoundShield product and technology. In addition, Sanuwave will bear the costs and clinical validation responsibilities associated with obtaining approval for WoundShield from the U.S. Food and Drug Administration and other regulatory agencies around the world, as discussed above.

Business Model

All of our products consist of a reusable controller device and a disposable component, or transducer. The controllers have a life expectancy of up to three years, while the disposable transducer has a life expectancy of up to a month and must be replaced to provide the intended therapy. The components are purchased by either the distributor or end user for use in any of the intended applications. Once the controller is purchased by the end user, recurring revenue will be realized by purchases of replacement transducers to the extent that the end user continues treatment with our product.

Our products are intended to be distributed both by independent distributors as well as by potential licensees. Distributor cost is discounted to account for their intended margins, based upon purchase volumes and/or periodic purchase commitments, with the disposable transducer sold and distributed in the same fashion. We currently have an established distributor network and are implementing certain criteria within such network to ensure the appropriate assignment of a distributor or licensee. We also intend to add additional distributors to our network.

In August 2019, we established our first license agreement with Medisana, Inc. ("Medisana") with a total of 1,500 devices that was shipped to Medisana directly from China, in April 2020. The devices were designed to carry the product labeling specific to the Medisana brand, with the product name of PT100. The product labeling includes the words, "PAINSHIELD Ultrasonic therapy, Medisana". All instructions for use and packaging are specific to Medisana.

In December 2020, we amended and restated our original distribution agreement with Ultra Pain Products, Inc. ("UPPI"). Under the terms of the new agreement, which extend the term and increase minimum purchase requirements, UPPI will be the exclusive distributor of privately labeled PainShield® and PainShield® Plus™ devices to the Durable Medical Equipment (DME) distribution sector of the healthcare market in the United States. By this new private label agreement, we have expanded our revenue opportunity with UPPI, effectively increasing what was an initial revenue target of $1.1 million over two years to $7.8 million over three years.

Our business plan continues to focus on these types of transactions/agreements. We continue to focus on the foundational aspects of each respective product, including the design and performance of each, the reimbursement, regulatory status, and quality control, in order to strengthen our position with prospective partners.

Ultrasound Technology and Our Products

As noted above, our primary products are based on the use of low frequency ultrasound, which delivers energy through mechanical vibrations in the form of sound waves. Ultrasound has long been used in physical therapy, physical medicine, rehabilitation and sports medicine.

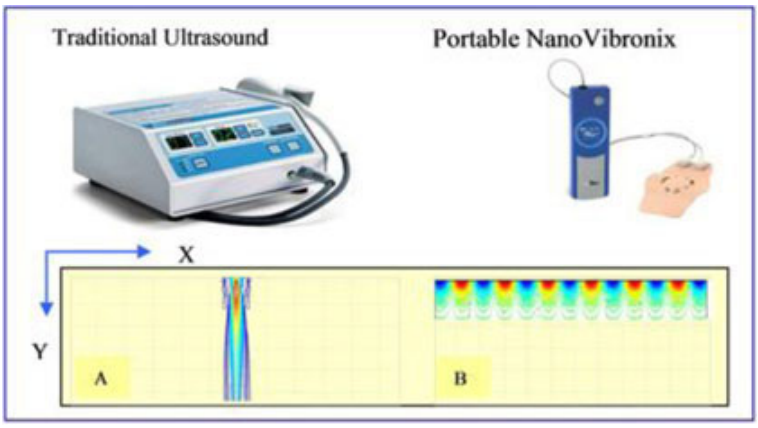
Our proprietary technology consists of a small, thin (1 millimeter) transducer that is capable of transmitting ultrasonic acoustic waves onto treatment surfaces with a radius of up to 10 centimeters beyond the transducer. This technology allows us to treat wounds by implanting our transducers into a small, portable self-adhering acoustic patch, thereby eliminating the need for technicians and medical personnel to manually administer ultrasound therapy, which should reduce the cost of therapy. Moreover, we believe that, based upon the body of evidence, the delivery of ultrasound through our portable devices is equal to or more effective than existing competitive products, as our technology is better positioned to target the affected areas of the body.

While there are currently a number of products on the market that treat pain through ultrasound therapy, we believe that our products differentiate themselves because they are portable, without the requirement to be plugged into an outlet and they have a frequency of 100kHz (in contrast to other devices, which have a frequency of 1MHz), which means our products do not produce heat that can damage tissue. Our products can therefore (i) be self-administered by the patient without the need to be moved about the treated area by the patient or a clinician, (ii) be applied for a significantly longer period without the risk of tissue damage and (iii) do not require the use of gel. We are aware of one competitive product with similar ultrasound technology, the SAM® Sport4 by a company called Zetroz Systems LLC, aka ZetrOz, Inc. However, it is our belief that this product does not generate surface acoustic waves as our products do, the treatment area is generally limited to that of the transducer’s diameter, the use of transmission gel is still required and the transducer thickness is significantly greater than ours (approximately 1.5cm). To our knowledge, the device only provides a battery life of 4 hours and is continuous therapy versus intermittent therapy.

There has been an article published in 2019 on SAM® Sport4 regarding clinical evidence demonstrating that ultrasound dose timing (i.e. daily treatment) and duration significantly impact benefits and treatment results, we are aware of a prospective randomized, double-blinded, placebo-controlled study on the effects of the long-duration low-intensity ultrasound treatment using SAM® Sport4 suggesting that ultrasound may be used as a conservative non-pharmaceutical and non-invasive treatment option for patients with knee osteoarthritis.

In general, ultrasound offers the benefits by increasing local blood circulation, increasing vascular wall permeability, promoting protein secretion, promoting enzymatic reactions, accelerating nitric oxide production, promoting angiogenesis (the formation of new blood vessels from pre-existing vessels) and promoting fibroblast proliferation (fibroblasts are a type of cell that play a critical role in wound healing). We believe that the body of evidence, and the positive therapeutic effect that ultrasound has for various indications, potentially provides for future product development opportunities for us.

Our proprietary technology consists of a small, thin (1 millimeter) transducer that is capable of transmitting ultrasonic acoustic waves onto treatment surfaces with a radius of up to 10 centimeters beyond the transducer. This technology allows us to treat wounds by implanting our transducers into a small, portable self-adhering acoustic patch, thereby eliminating the need for technicians and medical personnel to manually administer ultrasound therapy, which should reduce the cost of therapy. Moreover, we believe that, based upon the body of evidence, the delivery of ultrasound through our portable devices is equal to or more effective than existing competitive products, as our technology is better positioned to target the affected areas of the body.



Traditional ultrasound device and our portable ultrasound patch-based device and a comparison of their energy distribution, where the X-axis represents treatment surface and the Y-axis represents ultrasound energy penetration depth within tissue.

In a comparison of a traditional ultrasound device and our portable ultrasound patch-based device, the bulk wave conventional ultrasound machines with handheld transducers distribute the energy deeply into the body, as shown above in diagram (A) on the left. In comparison, our device distributes the energy on the surface, as shown in diagram (B), thereby meaningfully increasing the treatment area. Our transducers may also be incorporated into treatment patches, including patches that are designed to deliver medicine and other compounds through the skin. The generation and delivery of low frequency ultrasound over a period of time to a specific area has been termed “targeted slow-release ultrasound”. We believe that this delivery method of ultrasound may be comparable to that of slow release medication in the pharmaceutical industry. This “targeted slow-release” capability is intended to allow for more frequent targeting of the intended treatment area and thus may result in a more effective therapeutic response.

Micro Vibrations Technology and Our Products

It is well established that increasing blood flow to the wound and peri-wound area helps accelerate the healing of ischemic wounds. Micro-vibrations applied on the skin tissue increase local blood flow and oxygen delivery to the wound area and stimulate angiogenesis and growth factors that are helpful for the wound healing process. Vibration therapy has been found to stimulate blood flow due to mechanical stresses of endothelial cells resulting in increased production of nitric oxide and vasodilation, as well as increase soft tissue and skin circulation. (Maloney-Hinds et al., “The Role of Nitric Oxide in Skin Blood Flow Increases due to vibration in healthy adults and adults with type 2 diabetes,” School of Medicine, Loma Linda University. Ca. Diabetes Technology & Therapeutics, 2009 p. 39-43). In addition, micro vibrations induce skin surface nerve axon reflex and type IIa muscle fibers contraction rates, resulting in vasodilation (Nakagami et al., “Effect of vibration on skin blood flow in an in vivo microcirculatory model”, The University of Tokyo, Bio-Science Trends 2007; 1 (3): 161-166). Ten minutes of vibration therapy with laser doppler revealed a consistent increase in water content of the upper dermis (TJ Ryan et al., “The effect of mechanical forces (vibration or external compression) on the dermal water content of the upper dermis and epidermis, assessed by high frequency ultrasound”, Oxford Wound Healing Institute, Journal of Tissue Viability, 2001. In another study, mean blood flow increase was higher in the vibration group than the placebo group. Improvements in local blood flow may be beneficial in the therapeutic alleviation of pain or other symptoms resulting from acute or chronic injuries (C. Button et al., “The effect of multidirectional mechanical vibration on peripheral circulation of humans”, University of Otago New Zealand, Clinical Physiology and functional Imaging, 2007 27, p211-216). A study on the effect of whole body vibration on lower extremity skin blood flow suggests, that short duration vibration alone significantly increases lower extremity skin blood flow, doubling skin blood for a minimum of 10 minutes following treatment (Lohman et al., “The effect of whole body vibration on lower extremity skin blood flow in normal subjects”, Department of Physical Therapy, Loma Linda university, USA, Med Sci Monit, 2007; 13(2) 71-76). Vibration has also been shown to stimulate angiogenesis and growth factors such as vascular endothelial growth factor (Suhr F et al., “Effects of short-term vibration and hypoxia during high intensity cycling exercise on circulating level of angiogenic regulators in humans”, J Appl Physiol, 2007, 103:474-483, Yue Z. et al., “On the cardiovascular effects of whole-body vibration I. Longitudinal effects: hydrodynamic analysis”, Studies Appl Math, 2007, 119:95-109). Of import with respect to diabetic wounds, in which a prolonged inflammatory phase occurs, vibration vasodilation has generated an indirect anti-inflammatory action, mainly by suppression of nuclear factor-kβ, the key gene for inflammatory mediators (Sackner, M.A., “Nitric Oxide is released into circulation with whole-body, periodic acceleration”, Chest 2005;127;30-39).

Urinary catheter usage is associated with pain and discomfort caused by the friction between the catheter surface and the urethral tissue. Generally, this friction is treated by applying lubricating gels and low friction catheter coatings. These methods are effective for a short term during the catheter insertion as the lubricating gel is quickly absorbed into the surrounding tissue and loses its effect and the catheter coatings lose their lubricity within a few days, as the coating is covered by a thin film of mucous.

Our UroShield product provides vibrations along the surface of the urinary catheter that is in contact with urethral tissue. We believe that these vibrations create a continuous acoustic lubrication effect along the surface of the indwelling catheter that is in contact with the surrounding tissue, thus reducing catheter-tissue contact time, which may lessen trauma from urethra abrasion and adhesion. We have also shown in animals and in humans that the micro-vibration technology can reduce the level of biofilm formation on urinary catheters.

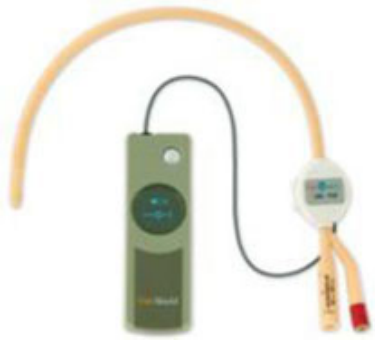
Our Products

Product Design, Packaging, Identity

All products were redesigned in the fourth quarter 2019, with an updated look and improved performance. These new designs were coupled with new branding, packaging, instructional manuals, and marketing materials. Beginning in the fourth quarter of 2019, our manufacturers in China have commenced producing the redesigned products for distribution and delivered their first completed units in April 2020.

UroShield

UroShield is intended to prevent bacterial colonization and biofilm formation, increase antibiotic efficacy in the catheter lumen and decrease pain and discomfort associated with urinary catheter use. It is designed to be used with any type of indwelling urinary catheter regardless of the material or coating. We believe that UroShield may be the first medical device on the market that attempts to simultaneously address all of the aforementioned catheter-related issues. UroShield is similar in design to WoundShield and PainShield, in that it uses a driver unit that produces low frequency, low intensity ultrasound. The driver unit connects to a disposable transducer that is clipped onto the external portion of the catheter to deliver ultrasound therapy to all catheter surfaces as well as the tissue surrounding the catheter.



Picture of UroShield with actuator

We believe the UroShield system has the following advantageous effects:

- **Prevention or Reduction of Biofilm.** The low frequency ultrasound generated by UroShield has been shown to decrease adherence of bacteria to catheter surfaces, thereby reducing biofilm. Biofilm is the complex matrix required for bacteria to grow and cause infection. See the discussion of our Heidelberg 1 trial below.

- **Decreased Catheter Associated Pain and Discomfort.** We believe that UroShield creates an acoustic envelope on the surfaces of the catheter, which decreases friction and tissue trauma, pain and discomfort caused by the catheter. In addition, in vivo (rabbit) studies have shown the tissue in contact with the catheter remains healthier and less traumatized as a result of the application of low frequency and low intensity ultrasound (Applebaum I, et.al., "The Effect of Acoustic Energy Induced By UroShield on Foley Catheter Related Trauma and Inflammation in a Rabbit Model" Department of Urology, Shaarey Zedek Medical Center and the Hadassah Hebrew University Medical School).

- **Acoustically Augmented Antibiotic Therapy.** Antibiotic resistance in biofilm bacteria is a well-known phenomenon. Although it has been known that ultrasound can increase antibiotic efficacy in in-vitro models, we do not believe that there has been a practical ultrasound-based medical device that was able to augment antibiotic efficacy in the clinical setting. In a clinical study, UroShield technology has been shown to eradicate biofilm-residing bacteria by greater than 85% when applied simultaneously with an antibiotic in three clinically relevant species, escherichia coli, staphylococcus epidermidis and pseudomonas aeruginosa (Banin E, et al., "Surface acoustic waves increase the susceptibility of Pseudomonas aeruginosa biofilms to antibiotic treatment," Biofouling, August 2011; we supplied devices for this study, but had no further involvement with it).

- **Preservation of the Patency of Catheters.** We believe that low frequency ultrasound applied to catheters will add an anti-clogging effect and will preserve patency of catheters. This effect is achieved by ultrasound waves creating an acoustic layer on the inner lumen of the urinary catheter, thereby preventing adherence of biological material and biofilm formation. We believe that this anti-clogging benefit will help prevent local infection and sepsis secondary to catheter obstruction.

UroShield has undergone a number of clinical trials. The Heidelberg 1 trial, conducted in 2005-2006, which we sponsored, was a 22 patient randomized, double blind, sham-controlled, independent trial that tested UroShield's safety and ability to prevent biofilm in patients with an indwelling Foley catheter. The trial demonstrated that UroShield prevented biofilm in all patients with the active device as compared to biofilm being found in seven of eleven of the control patients. In addition, there was a marked decrease in pain, discomfort and spasm in the active UroShield patients, as evidenced by a statistically significant decrease in the requirement for the medications required to treat urinary catheter associated pain and discomfort (Ikinger U, "Biofilm Prevention by Surface Acoustic Nanowaves: A New Approach to Urinary Tract Infections?," 25th World Congress of Endourology and SWL, Cancun, Mexico, October 2007).

In a subsequent physician-sponsored trial, known as Heidelberg 2, conducted in 2007, 40 patients who underwent radical prostatectomies were divided into two groups, with the active group receiving one intra-operative dose of antibiotics and UroShield and the control group receiving one intra-operative dose of antibiotics and then five subsequent doses over three days. At the end of the trial, the control group had four cases of bacteriuria, as compared to one in the active group. In a third trial, a physician-sponsored open label trial, 10 patients who received emergency placement of a urinary catheter due to acute obstruction were given a UroShield device and followed with regard to their pain, discomfort, spasm and overall well-being. Within 24 hours, all patients showed improvement and increased toleration of the catheter (Zillich S., Ikinger U, "Biofilmprävention durch akustische Nanowellen: Ein neuer Aspekt bei katheterassoziierten Harnwegsinfektionen?," Gesellschaft für Urologie, Heilbronn, Germany, May 2008). We supplied devices for this trial, but had no further involvement with it.

As recently announced, the Company submitted to The National Institute for Health and Care Excellence, for review, the findings from an independent evaluation of its UroShield® device on patients who had used the device for up to two years. Clinical data from the study conducted by Coventry University's Assistant Professor, Ksenija Maravic da Silva, during 2020 reported statistically significant outcomes for the device including a reduced number of urinary tract infections (UTIs), reduced instances of prescribed antibiotics, reduced catheter blockages, reduced the need for unplanned catheter changes and reduced pain reported as a result of catheter associated complications. The study also provided important insights into the lives of those using the device including improvement of overall well-being, relating specifically to decreased levels of worry and increased ability to socialize. In addition, patient feedback on product improvements was addressed and has been incorporated in the present commercially available device.

Market for UroShield

According to the Centers for Disease Control and Prevention, urinary tract infection (UTI) is an infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney. UTIs are the most common type of healthcare-associated infection reported to the National Healthcare Safety Network (NHSN). Among UTIs acquired in the hospital, approximately 75% are associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine. Between 15-25% of hospitalized patients receive urinary catheters during their hospital stay. The most important risk factor for developing a catheter-acquired urinary tract infection (CAUTI) is prolonged use of the urinary catheter.

This study was written up in the December 2018 issue of “Medical & Surgical Urology”, a leading peer-reviewed journal in the field of urology.

Approximately 15-25% of patients who are admitted to a hospital will have an indwelling catheter at some point during their stay and 7% of nursing home residents are managed by long term catheterization.

CAUTI is the most common nosocomial infection in hospitals and nursing homes, representing over 40% of all hospital-acquired infections (HAIs) and 20% of intensive care unit HAIs (Maki, P and Tambyah, D. Engineering Out the Risk for Infection with Urinary Catheters., Emerging Infectious Diseases., Vol. 7, No. 2, March–April 2001). In addition, CAUTIs are the source for approximately 20% of healthcare acquired bacteremia in acute care and 50% in long-term care facilities (Nicolle, Lindsay E. “Catheter Associated Urinary Tract Infections.” Antimicrobial Resistance and Infection Control 3 (2014). The risk of acquiring CAUTI depends on the method and duration of catheterization and patient susceptibility. Patients requiring a urinary catheter have a daily risk of approximately five percent of developing bacteriuria and approximately 25% of patients develop nosocomial bacteriuria or candiduria over one week (Maki, P and Tambyah, D. Engineering Out the Risk for Infection with Urinary Catheters., Emerging Infectious Diseases., Vol. 7, No. 2, March–April 2001). Virtually all patients requiring indwelling urinary catheters for longer than a month become bacteriuric.

CAUTI occurs because urethral catheters inoculate organisms into the bladder and promote colonization by providing a surface for bacterial adhesion and causing mucosal irritation. The presence of a urinary catheter is the most important risk factor for bacteriuria. Once a catheter is placed, the daily incidence of bacteriuria is 3-10%. Between 10% and 30% of patients who undergo short-term catheterization (i.e., 2-4 days) develop bacteriuria and are asymptomatic. Between 90% and 100% of patients who undergo long-term catheterization develop bacteriuria. About 80% of nosocomial UTIs are related to urethral catheterization; only 5-10% are related to genitourinary manipulation. (John L. Brusch, Catheter-Related Urinary Tract Infection, Medscape, August 18, 2015).

The global catheter market size was valued at USD 37.3 billion in 2018 and is expected to witness a CAGR of 9.7% through 2026. Rising prevalence of chronic disorders leading to hospitalization has fueled the growth of this market. Presence of multi-national manufacturers, improving medical facilities, supportive insurance policies are also some of the key factors propelling the market growth. North America is the largest regional market due to the presence of multi-national manufacturers and sophisticated healthcare infrastructure along with high product awareness levels. Asia Pacific is projected to expand at the maximum CAGR of 10.4%, over the study period. According to a Grandview research report published 2018, there are 25 million Foley catheters sold annually in the United States and 75 million catheters sold elsewhere yielding a total global Foley catheter market of 100 million units worldwide. The cost to treat a simple CAUTI has been estimated at $13,793 per case (AHRQ), and the cost of treating bacteremia has been estimated at $8,355 (NIH) per case, yielding a total healthcare burden of $830 million per year. While there are currently both antibiotic and silver coated catheters in the market, they often sell for approximately $10 above the non-antimicrobial equivalent.

In addition, as of October 1, 2008, Medicare stopped authorizing its payment to hospitals in which patients have developed a catheter-associated urinary tract infection that was not present on admission. This provides hospitals in the United States with a substantial financial incentive to reduce the occurrence of such infections through the use of products such as UroShield, which help prevent infections hospitals would otherwise have to treat without reimbursement. In addition, it has been noted that the Centers for Medicare & Medicaid Services may fine hospitals in the future when their patients develop CAUTI, which will likely increase the incentive of hospitals to invest in technologies that may prevent this complication (Brown J, et al. “Never Events: Not Every Hospital-Acquired Infection Is Preventable, Clinical Infectious Diseases, 2009, 49 (5)).

Competition for UroShield

Several types of products have been introduced to address the growing problem of catheter-acquired infection and biofilm formation on catheter surfaces. Manufacturers offer antibiotic-coated and antiseptic-impregnated catheters. In addition, manufacturers have produced silver-coated catheters, which have been shown in small studies to delay bacteriuria for about two to four days. However, larger studies did not corroborate this result; on the contrary, silver hydrogel was associated with overgrowth of gram positive bacteria in the urine (Riley DK, Classen DC, "A large randomized clinical trial of a silver-impregnated urinary catheter: lack of efficacy and staphylococcal superinfection," Am. J. Med. 1995 April; 98(4):349-56).

UroShield has been designed to be added to any type of catheter, including Foley catheters and silver-coated catheters, to improve a catheter's infection prevention performance. UroShield is not intended to replace any existing products or technologies, but instead is intended to assist these existing products or technologies in preventing catheter-acquired urinary injury and catheter associated complications. While UroShield has been approved by the U.S. Food and Drug Administration ("FDA") under Enforcement Discretion during the COVID-19 health emergency, if we do not obtain permanent clearance from the FDA, UroShield may be unable to successfully compete in this market due to an inability to obtain such permanent clearance from the FDA and failure to be adopted by health care practitioners and facilities.

Regulatory Strategy

UroShield received CE Mark approval in September 2007 and was also approved for sale by the Israeli Ministry of Health in 2008. We are able to sell UroShield in India and Ecuador based on our CE Mark. UroShield was granted a Canadian medical device license in September 2016, although, due to a modification of regulatory standards in Canada, we have lost our Canadian license. We are working toward reinstatement of our Canadian license. To that extent, we passed an audit in November 2020 with a notified body and we are waiting on a certificate.

In the European Union, UroShield has been marketed for the prevention of biofilm, decreased pain and discomfort associated with urinary catheters and increased antibiotic efficacy.
In September 2020, the FDA exercised its Enforcement Discretion to allow distribution of the UroShield device in the United States. According to the FDA, "UroShield® device can use Intended Use Code (IUC) 081.006: Enforcement discretion per final guidance, and FDA product code QMK (extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic)".

Accordingly, the FDA's Enforcement Discretion clears the way for import of UroShield to the U.S. during the Covid-19 pandemic, immensely expanding the company's addressable market for the device during this time period. The device is designed to aid in the prevention of CAUTI incidence in patients requiring long-term indwelling catheterization.

After reviewing the body of scientific evidence that we presented, the FDA took decisive action to clear the way for patient access to UroShield for the duration of the Covid-19 pandemic. The evidence presented to the FDA on UroShield demonstrated decreases in the risk of catheter-associated urinary tract infections and related complications in patients using UroShield who required long-term indwelling catheterization. Importantly, we are unaware of any other commercially available device that can prevent catheter-associated urinary tract infection incidence and achieve results comparable to UroShield.

We intend to seek 510K clearance from the U.S. Food and Drug Administration through the de novo classification process for UroShield. We are currently seeking advice from the FDA prior to submission.

Studies completed to establish safety of UroShield for human use:

- A large animal model (female sheep) study has been conducted to establish local tissue response from a urinary catheter with UroShield attached as compared to a control group of animals with a urinary catheter with no UroShield attached.

  The pre-clinical animal study was intended to demonstrate safety of UroShield device when used for 30-days with a urinary catheter. The study compared local tissue and organ response in two groups of 4 (female) sheep where one group was catheterized (urethral) using an uncoated silicone Foley catheter (only) and the other group was catheterized using an uncoated silicone Foley catheter with UroShield device attached to it. All catheters were identical in their size, material composition and manufacturer.

  After 30 days the animals were euthanized and local tissue and organs were examined. The results showed the group with UroShield device had fewer observations of swelling, redness or discharge at the vulva as compared to the group without UroShield. The animals did not exhibit signs of discomfort or pain during study period (of 30 days). The gross and histopathology findings were also very similar between the two groups.

- A comparative study of leachables from a urinary catheter with and without UroShield attached has been performed to demonstrate that the leachables with UroShield attached do not exceed toxicological safe limits allowed for a medical device.

  The chemical characterization of leachables was intended to demonstrate safety for UroShield device for 30-day use with a urinary catheter. The study compared leachables from a group consisting of 3 uncoated silicone catheters with leachables from a group consisting of 3 uncoated silicone catheters with UroShield attached to it. All catheters were identical in their size, material composition and manufacturer.

  The exhaustive extractions were performed with non-polar, polar and aqueous solvents. An additional simulated use extraction using Saline and Ethanol was performed. Overall the extractables from both groups were comparable and toxicological evaluation showed that all compounds from extraction with UroShield were below the tolerable exposure limits. Most of compounds had a margin of safety greater than 10 and 4 compounds had margin of safety between 1.5 and 10. Overall, the toxicological risk for using UroShield with a urinary catheter is similar and at even lower as compared to a catheter without UroShield attached.

Sales and Marketing

Since the FDA exercised its Enforcement Discretion to allow the distribution of the UroShield device in the United States, we have been actively seeking partnerships for marketing our product in the United States. We believe the business opportunity for UroShield is in the hundreds of millions in U.S. dollars to the extent that UroShield obtains permanent 510(k) clearance from the FDA, is recognized as effective and becomes widely adopted for use in catheters. To that end, we are seeking a strategic partnership with various companies which have an existing “footprint” in the Urology market. Those discussions and negotiations are ongoing at this time. We have appointed distributors for UroShield in the United Kingdom and, and an outside management organization, Morulaa Health, to assist with regulatory matters and distribution of UroShield in India. Each of these distributors is paid a small retainer and will be paid a commission between 10 to 20% of sales going forward. Total payments to these distributors totaled under $10,000 in 2020.

We announced in May 2020, that we had expanded our license agreement with Ideal Medical International Limited to include exclusive rights to distribute the Company’s UroShield® and PainShield® technologies in Canada and Turkey.

From time to time we have had interest from strategic companies in the catheter market to partner, license or acquire the UroShield technology. These strategic partners are active in the urology market and may be interested in integrating UroShield as an accessory, into its range of products. Discussions with these partners are ongoing.

Clinical Trials

To date, we have conducted the clinical trials set forth below:

Purpose	**Doctor/Location**	**Time, subjects**	**Objectives**	**Results**
To assess the safety of the UroShield Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD1)	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2005-2006 22 patients	To demonstrate that the use of the UroShield is safe and that the device is well tolerated by the patients and user friendly to the medical staff. Efficacy objectives were to demonstrate that the UroShield helps in prevention of biofilm formation in comparison with the urinary catheter alone, as well as bacteriuria.	UroShield was both safe and well tolerated. UroShield proved efficacious in prevention of biofilm. Subjects required significantly less medications than the control group for catheter related pain and discomfort.
Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD2 **)** Physician initiated	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2007 40 patients	To demonstrate that the use of the UroShield is safe and helps in prevention of biofilm formation and UTI in comparison with the urinary catheter alone, as well as decrease antibiotic use.	In this trial, only 1/20 patients in UroShield device (no antibiotics) group developed urinary tract infection compared to 4/20 patients within control group treated with the antibiotic prophylaxis alone.
The Effect of UroShield on Pain and Discomfort in Patients Released from the Emergency Room with Urinary Catheter Due to Urine Incontinence Physician initiated	Shaare Zedek Medical Center Jerusalem, Israel.	2007 10 patients	The study aimed to assess the effectiveness of the UroShield in reducing pain and discomfort levels and improve the well-being of the subjects. Efficacy objectives included reduction of pain, spasm, burning and itching sensation levels of the subjects.	The results demonstrated a reduction in pain, itching, burning and spasm levels. Additionally, the well-being of the subjects showed a significant increase.
The Use of the UroShield Device in Patients with Indwelling Urinary Catheters Open labeled, comparative, randomized study	Dr. Shenfeld Shaare Zedek Medical Center Jerusalem, Israel.	2007-2009 40 patients	Patient complaints related to catheter regarding pain according to VAS scale and discomfort according to 0-10 scale Presence of Clinically Significant UTI Presence of Bacteriuria Presence of Biofilm Use of medication	UroShield device was effective in reducing postoperative catheter related pain discomfort and bladder spasms. There was also a notable trend towards reduction of bacteriuria.

Purpose	Doctor/Location	Time, subjects	Objectives	Results
Evaluation of the UroShield in urinary and nephrostomies to reduce bacteriuria Physician initiated	Prof. P.Tenke, Hungary	2010-2011 27 patients	● Pain, disability and QOL ● Catheter patency ● Bacteriuria / UTI ● Hospitalization period ● Analgesics and Antibiotics intake	Showed reduction in pain and significant decrease in bacteriuria rate.
Double Blind, Randomized Control Study for Prevention of Bacterial Colonization and UTI associated with Indwelling Urinary Catheters	Dr. Shira Markowitz Buffalo, NY	2017 55 patients	To demonstrate the use of the UroShield reduces bacterial colonization on the urinary catheter	Final results entitled “The Effect of Surface Acoustic Waves on Bacterial Load and Preventing Catheter-Associated Urinary Tract Infections (CAUTI) in Long Term Indwelling Catheters,” which was published in the December 2018 issue of Medical & Surgical Urology, a leading peer-reviewed journal in the field of urology. Mean improvement advantage in treatment vs control was 87.2K CFU, (t (53) 18.1, $p<0.001$) at thirty days. At 60 days the mean improvement advantage in treatment vs control was 87.5K CFU, (t (53) 18.1, $p<0.001$). At 90 days the mean improvement advantage in treatment vs control was 79.3K CFU, (t (53) 12.4, $p<0.001$).

Purpose	Doctor/Location	Time, subjects	Objectives	Results
				After cessation of treatment in the active group at 30 days, there was a minimal increase in CFU count at both 60 and 90 days. In the same group, there was no statistical difference in the decrease of CFU count from 30 to 60 days after treatment, t (28)=1. p= .326, however there was a marginally significant increase in CFU from 60 to 90 days for the active group (28)=1.7 p= 0.09. At baseline, every enrolled patient had been treated for infection during the 90 days prior to enrollment. Compared to baseline, the treatment group showed significant statistical and clinical improvement (100%) at 30 days relative to the sham control (73%). There were no reported infections in the Treatment Group while in the control group there were seven reported infections. At 90 days after treatment, the treatment group showed a significantly stronger improvement (89.7%) compared to the sham control (46.2%). There were three reported infection in the Treatment group, while in the control group there were fourteen reported infections requiring antimicrobial therapy. (logistic regression B=2.3, Wald Chi-Square (df=1) =10.1, p=0.001.)

Purpose	Doctor/Location	Time, subjects	Objectives	Results
UroShield Randomized Control trial	5 different nursing facilities	2017 - 2018 51 subjects	51 subjects were evaluated with 26 in the active/treatment group and 25 in the control group. All patients had been treated for at least one incident of a catheter-acquired urinary tract infection (CAUTI) requiring antibiotics in the preceding 6 months prior to trial initiation.	At the 90-day evaluation, 13 of 25 subjects (52%) in the control group developed a CAUTI requiring systemic antibiotics while only 1 of 26 patients (4%) in the UroShield™ group required antibiotic. All study subjects had an initial colony count of greater than 100,000 CFU cultured from their urinary tract. At thirty days, all subjects within the control group showed no change in the number of their bacteria count which was greater than 100,000 CFU, while those in the treatment group showed a reduction to 10,000 CFU in 15 of 26 subjects and only 1,000 CFU in 10 of 26 subjects, proving a decrease in both bacterial colonization and the incidence of Urinary Tract Infection.

Recently Completed, Current, Ongoing and Planned Clinical Trial

In July 2019, a 23 -patient trial was completed in Norwich, United Kingdom. The trial was initiated to satisfy the requirements for adoption within the UK National Health Service. Results of the trial have not been published. The hospital that completed the patient trial continues to use the UroShield device.

In September 2019, an economic impact study was performed completed by York Health Economic Consortium, United Kingdom to determine the cost savings related to prevention of urinary tract infection. The study resulted in an economic impact "model" which will demonstrate cost savings to prevention of patients contracting UTI. The trial was initiated to satisfy the requirements for adoption within the UK National Health Service.

In April 2019, an in vitro study was performed at Southampton University, Southampton, United Kingdom, to determine the effect of UroShield on bacterial colonization in a laboratory setting. The trial was initiated to satisfy the requirements for adoption within the UK National Health Service. This trial will also be helpful to fulfill a requirement of the FDA. Results revealed positive results to all others studied in the same laboratory.

UroShield-In vivo study is being conducted by Dr. Blayne Welk MD MSc and Dr. Jeremy Burton MSc PhD. The study, entitled "Low energy surface waves to prevent urinary infections and catheter associated symptoms among patients with neurogenic bladder dysfunction". The intent is to conduct a pilot study to determine if the UroShield device can reduce catheter symptoms, improve urinary quality of life, and reduce catheter biofilm formation and bacteriuria among patients with neurogenic bladder dysfunction and an indwelling catheter. The study is ongoing but the recruitment has slowed due to the Covid-19 pandemic.

This study is being done without cost to NanoVibronix and is expected to be presented at the American Urologic Association in the fall.

If we are able to locate a strategic partner or otherwise obtain sufficient funding, we anticipate conducting the following clinical trial:

Trial	Place	Start Date/Timing	Objectives
UroShield U.S. Food and Drug Administration trial 80 patient trial	To be determined	To be determined	Safety and efficacy of UroShield in urinary catheter related pain and infection and biofilm formation. The results of previous clinical trials may not be predictive of future results, and the results of our planned clinical trial, if we are able to locate a strategic partner or otherwise obtain sufficient funding, may not satisfy the requirements of the FDA.

PainShield®

PainShield is an ultrasound device, consisting of a reusable driver unit and a disposable patch, which contains our proprietary therapeutic transducer. It delivers a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area, while keeping the level of ultrasound energy at a safe and consistent level of 0.4 watts. We believe that PainShield is the smallest and most portable therapeutic ultrasound device on the market and the only product in which the ultrasound transducer is integrated in a therapeutic disposable application patch.

The existing ultrasound therapy devices being used for pain reduction are primarily large devices used exclusively by clinicians in medical settings. PainShield is able to deliver ultrasound therapy without being located in a health care facility or clinic because it is portable, due to it being lightweight and battery operated. Because it is patch based and easy to apply, PainShield does not require medical personnel to apply ultrasound therapy to the patient. The patient benefits include ease of application and use, faster recovery time, high compliance, and increased safety and efficacy over existing devices that rely on higher-frequency ultrasound (Adahan M, et al, "A Sound Solution to Tendonitis: Healing Tendon Tears With a Novel Low-Intensity, Low-Frequency Surface Acoustic Ultrasound Patch," American Academy of Physical Medicine and Rehabilitation Vol. 2, 685-687, July 2010). PainShield can be used by patients at home or work or in a clinical setting and can be used even while the patient is sleeping. Its range of applications includes acute and chronic pain reduction and anti-inflammatory treatment.

Picture of PainShield with Patch

PainShield is used to treat tendon disease and trigeminal neuralgia (a chronic pain condition that affects the trigeminal or 5th cranial nerve, one of the most widely distributed nerves in the head); previously, the therapeutic options for these disorders have been very limited. PainShield has also been used to treat pelvic and abdominal pain. To date, to the best of our knowledge, the only treatment options for these conditions are pain medication and surgery. Several additional causes of pain, and the treatment of that pain with the PainShield product, can be explored through clinical trials.

Market for PainShield

Pain-related complaints are one of the most common reasons patients seek treatment from physicians (Prince V, "Pain Management in Patients with Substance-Use Disorders," Pain Management, PSAP-VII, Chronic Illnesses). According to Landro L, "New Ways to Treat Pain: Tricking the Brain, Blocking the Nerves in Patients When all Else Has Failed," Wall Street Journal, May 11, 2010, approximately 26% of adult Americans, or approximately 76.5 million people, suffer from chronic pain. The National Center for Health Statistics has estimated that approximately 54% of the adult population experiences musculoskeletal pain. Studies have shown that low-frequency ultrasound treatment has yielded positive results for a variety of indications, including tendon injuries and short-term pain relief (Warden SJ, "A new direction for ultrasound therapy in sports medicine," Sports Med. 2003; 33 (2):95-107), chronic low back pain (Ansari NN, Ebadi S, Talebian S, Naghdi S, Mazaheri H, Olyaei G, Jalaie SA, "Randomized, single blind placebo controlled clinical trial on the effect of continuous ultrasound on low back pain," Electromyogr Clin Neurophysiol. 2006 Nov; 46(6):329-36) and sinusitis (Ansari NN, Naghdi S, Farhadi M, Jalaie S, "A preliminary study into the effect of low-intensity pulsed ultrasound on chronic maxillary and frontal sinusitis," Physiother Theory Pract. 2007 Jul-Aug; 23(4):211-8). We believe that PainShield's technology, portability and ease of use may result in it becoming an attractive product in the pain management and therapy field.

Competition

There are numerous products and approaches currently utilized to treat chronic pain. The pharmacological approach, which may be the most common, focuses on drug-related treatments with the over-the-counter internal analgesic market estimated at $19 billion in 2019. Alternatively, there are a large number of non-pharmacological pain treatment options available, such as ultrasound, transcutaneous electrical nerve stimulation, or TENS, laser therapy and pulsed electromagnetic treatment. In addition, there are some technologies and devices in the market that utilize low frequency ultrasound or patch technology. Many patients are initially prescribed anti-pain medication; however, ongoing use of drugs may cause substantial side effects and lead to addiction. Therefore, patients and clinicians have shown increased interest in alternative pain therapy using medical devices that do not carry these side effects.

The currently available ultrasound treatments for chronic pain have generally been accepted by the medical community as standard treatment for pain management. However, the traditional ultrasound treatments, such as those manufactured or distributed by Mettler Electronics Corp, Metron USA and Zimmer MedizinSysteme, are stationary devices found only in clinics and other health care facilities that need to be administered to patients by health care professionals. We are aware of three companies that market smaller ultrasound devices capable of certain self-administered use for the treatment of pain: Koalaty Products, Inc., Sun-Rain System Corp. and PhysioTEC. These devices generally function in the same manner, at the same frequency and with the same administration and safety requirements and limitations as traditional, larger ultrasound devices. We are also aware of one product, the SAM® Sport4, which has recently received U.S. Food and Drug Administration approval and also has CE Mark approval, marketed by ZetrOZ, Inc., that we understand may eliminate certain of these requirements and limitations, namely the requirement to be plugged in, the need for movement around the treated area and the relatively short safe treatment period. However, we understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that under the transducer, that the use of transmission gel is still required and that the transducer thickness is significantly greater than ours (approximately 1.5cm). It is also our understanding that the U.S. Food and Drug Administration has prohibited the manufacturer from labeling or promoting this product for use directly over bone that is near the skin surface. In addition, there are other patch-based methods of pain treatment, such as TENS therapy. TENS therapy may be painful and irritating for the patient due to the muscle contractions resulting from the electrical pulses. PainShield combines the efficacy of ultrasound treatment for pain with the ease of use and portability of a patch-based system. PainShield also may be self-administered by the patient, including while the patient is sleeping. However, if we are unable to obtain widespread insurance coverage and reimbursement for PainShield, its acceptance as a pain management treatment would likely be hindered, as patients may be reluctant to pay for the product out-of-pocket.

The CMS has approved PainShield for reimbursement for Medicare beneficiaries on a national basis effective January 2020.

Regulatory Strategy

PainShield received 510(k) clearance from the U.S. Food and Drug Administration in August 2008 for treatment of pain relief. PainShield received CE Mark approval in July 2008 and was also approved for sale by the Israeli Ministry of Health in 2010. We are able to sell PainShield in India and Ecuador based on our CE Mark. We are in discussions with a distributor in Southeast Asia, and, if a distributor is engaged, intend to seek regulatory approvals for PainShield in Southeast Asia through such distributor.

In the United States, a prescription from a licensed healthcare practitioner is required for the use of PainShield. We have engaged a consultant to assist us in the process of reclassifying the next generation of PainShield devices to remove the prescription requirement for the use of PainShield. We believe that such reclassification will open up mass market opportunities which are currently not available to us due to the prescription requirement. However, there is no assurance that we will be able to remove the prescription requirement for the use of PainShield or that, even if we accomplish such reclassification and the use of PainShield no longer requires a prescription, PainShield will be successful commercially in the mass market or we will be able to generate significant revenues from the mass market opportunities, if any.

In order to eliminate the requirement for a physician prescription, proof of safety and consumer “usability” must be established. With no adverse events reported on the PainShield device, we have a high degree of confidence that we will achieve the desired outcome. We have engaged User-View, Inc to facilitate our Usability study. The product packaging and all instruction documents have been modified to meet OTC standards. That study was completed in 2019 with positive results.

In the United States, PainShield falls under the diathermy classification for the treatment of pain for initial reimbursement purposes. The permitted reimbursement codes can be used in the outpatient supervised medical setting. We intend to coordinate with the Centers for Medicare and Medicaid Services and private insurers so that reimbursement can be extended to cover the administration of PainShield outside of health care facilities and clinics. In addition, we intend to conduct clinical trials in order to effectively market PainShield for a larger range of indications. The targeted reimbursement would be based upon specific indications, where study data serves as justification for payment.

Sales and Marketing

PainShield was introduced in 2009 as a treatment for pain, such as tendonitis, sports injuries, pelvic pain and neurologic pain and we have sold over 5,000 units since its introduction. We have entered into distribution agreements in United States, Europe, Asia and India for the distribution of PainShield. We intend to seek additional distribution opportunities in Europe, East Asia and Ecuador. In addition, we sell PainShield directly to patients through our website. We are currently ramping up our marketing efforts in the U.S. market and throughout the world to establish licensing and private label partnerships as well.

We have identified a unique and effective application for PainShield, the treatment of a severe facial nerve pain called Trigeminal Neuralgia, otherwise known as tic douloureux. Two studies were performed in Israel, “a randomized control trial examining the efficacy of low intensity low frequency Surface Acoustic wave ultrasound in trigeminal neuralgia pain”, and “A sound solution for Trigeminal Neuralgia”. Two trials which enrolled a total of 16 and 15 patients respectively, both conducted at the Sheba Medical Center in Israel, concluded that this study supports the hypothesis that the application of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound (LILF/SAW) may be associated with a clinically significant reduction of pain severity among patients suffering from trigeminal neuralgia disease. One of the studies showed a reduction in pain among 73% of the participants. We believe this to be an ideal market to address with the PainShield. With few existing treatment alternatives, we believe the PainShield’s effectiveness is a practical and safe alternative. A broader RCT, targeting 60 patients suffering from unilateral trigeminal neuralgia, was recently completed. The article was published on January 22, 2019, in the Journal of Anesthesiology and Pain Research, under the title “The Effect of a Surface Acoustic Wave (SAW) Device on the Symptomatology of Trigeminal Neuralgia”.

GlobalData’s epidemiological analysis forecasts that the total prevalent cases of trigeminal neuralgia in the seven major markets (United States, France, Germany, Italy, Spain, U.K and Japan) will grow at 15% between 2012 and 2022. According to an estimate by Ronald Brisman, M.D., in 2013 the prevalence of trigeminal neuralgia in the U.S. may have been as high as approximately 280,000 patients. With the favorable results from our current, ongoing study (explained in detail below), we continue to plan to aggressively pursue this market through direct marketing efforts and distributor relationships.

We have also identified a market for PainShield in the professional sports industry, where in some cases, reimbursement may be available from sports alumni organizations or, more likely, self-pay. In order to pursue this market, we are exhibiting at sports trainers meetings, pursuing alumni associations, advertising in their media, and have recently engaged a national distributor in the United States. Discussions and ongoing negotiations continue with other appropriate distributors in these various market segments.

Clinical Trials

To date, we have conducted or are in the process of conducting the clinical trials set forth below:

Purpose	**Doctor/Location**	**Time, subjects**	**Objectives**	**Results**
A sound solution for Trigeminal Neuralgia Physician initiated	Dr. Ch. Adahan Sheba Medical Center	2009 15 patients	●Reduction in pain ●Reduction in disability ●Improvement of function and quality of life ●Accelerating of healing	73% of the subjects experienced complete or near complete relief.
Randomized control trial examining the efficacy of low intensity low frequency Surface Acoustic wave ultrasound in trigeminal neuralgia pain For Ph.D., Funded by Israeli Ministry of Health	Dr. M. Zwecker Chaim Sheba Medical Center, Tel Hashomer, Israel	2012-2012 16 patients	●Reduction in pain ●Reduction in disability ●Improvement of function and quality of life ●Accelerating of healing	In conclusion this study supports the hypothesis that the application of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound (LILF/SAW) may be associated with a clinically significant reduction of pain severity among patients suffering from trigeminal neuralgia disease.

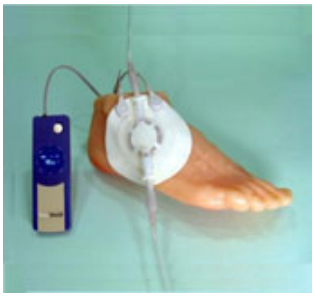
Purpose	Doctor/Location	Time, subjects	Objectives	Results
Treating Rutgers university athletic injuries with bandaid sized ultrasound unit PainShield	R. Monaco, G. Sherman, Rutgers University Athletic, Rutgers, New Jersey	2011 35 patients	●To assess the pain, functional capacity and discomfort of the subject ●To assess the subject's quality of life ●To assess the injury status ●To assess the efficacy of the treatment ●To assess compliance factors	Active group: 74% had improvement, 26% no change Sham group: 56% no change, 44% had improvement This is an indication of the effectiveness of the device. Lack of funding for statistical analysis has stopped this trial prior to fulfillment.
Reduction of chronic abdominal and pelvic pain, urological and GI symptoms using wearable device delivering low frequency ultrasound	D. Wiseman, Synechion Institute for Pelvic Pain	2011 19 patients	●To assess the efficacy of PainShield for pelvic and related pain	Improvement in pain related symptoms noted for all symptoms.
The Effects of the NanoVibronix's PainShield® Surface Acoustic Waves on the Symptoms of Lateral Epicondylitis	Dr. David Lemak, a leading orthopedic surgeon with Birmingham Orthopedic and Sports Specialists.	2019, 24 patients	A randomized, double blinded study for 30 days that evaluated the effectiveness and safety of PainShield™ Surface Acoustic Wave (SAW) technology on patients suffering from pain and discomfort, as well as limited mobility caused by the effects of chronic or acute lateral epicondylitis (LE) ("tennis elbow").	We plan to publish an article at the time and in conjunction with adding a marketing partner.
The Effect of a Surface Acoustic Wave (SAW) Device on the Symptomatology of Trigeminal Neuralgia	Shira Markowitz, MD, New York, NY	Early 2018 59 patients	To measure pain scores, quality of life, and breakthrough drug use of 59 patients with a diagnosis of unilateral trigeminal neuralgia.	There was a significant difference in the outcomes of the two groups relative to pain, quality of life, and breakthrough medications taken, which was directly correlated to pain experienced during treatment. Specifically, the treatment group experienced a 55.2% improvement in baseline pain scores versus 2.3% for the control group. The treatment group experienced a 46.4% reduction in breakthrough pain medication versus 1.5% for the control group.

If we are able to obtain sufficient funding, we anticipate conducting the following clinical trials:

Trial	Place	Start Date/Timing	Objectives
PainShield for Pelvic Pain 200 patient trial	To be determined	To be determined	Safety and Efficacy of PainShield in Chronic Pelvic Pain

WoundShield®

Our WoundShield product was granted the European Wound Closure Customer Value Leadership Award, Ultrasound Therapy – Wound Closure in 2014. WoundShield is intended to treat acute and chronic wounds with a disposable treatment patch that delivers localized therapeutic low frequency ultrasound. The WoundShield patch has two configurations: one that is placed adjacent to the wound and another, called the instillation patch, that is placed on the wound to enable instillation through sonophoresis, a process that increases the absorption of semisolid topical compounds, including medications, into the skin. Based on studies conducted by BIO-EC Microbiology Laboratory and Rosenblum, we believe that our WoundShield product possesses significant potential for the treatment of, among other things, diabetic foot ulcers and burns (Gasser P, Study Report delivered by BIO-EC Microbiology Laboratory, Dec 2007, which we ordered, paid for, and provided devices for; Rosenblum J, "Surface Acoustic Wave Patch Diathermy Generates Healing In Hard To Heal Wounds," European Wound Management Association 2011, for which we supplied devices but had no further involvement). In March 2020, we signed a license agreement with Sanuwave Health, Inc. ("Sanuwave") for the manufacture and delivery of our WoundShield technology. Under the terms of the agreement, NanoVibronix received 127,000 warrants of Sanuwave stock upon signing, will receive a $250,000 milestone payment based on FDA approval, and 10% royalty on Sanuwave's gross revenues from sales or rentals of WoundShield. In return, Sanuwave has received the worldwide, exclusive rights to the Company's WoundShield product and technology. In addition, Sanuwave will bear the costs and clinical validation responsibilities associated with obtaining approval for WoundShield from the U.S. Food and Drug Administration and other regulatory agencies around the world.

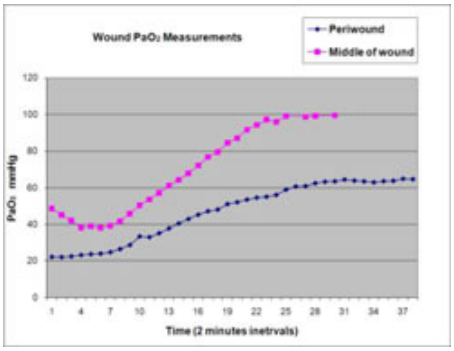


Picture of WoundShield Driver and Instillation Patch

WoundShield delivers surface acoustic waves to the location of the wound. Surface acoustic waves move laterally across the surface of the wound, which enables the transfer of the acoustic energy of the waves along the entire wound surface in a continuous and consistent mode, providing access to the waves' benefits for a longer treatment period than conventional ultrasound without the need for supervision or a treatment session by a clinician.

The technology has been found to have a positive effect on the epithelialization (healing by the growth of epithelial cells) of diabetic wounds, as well as on the stimulation of the precursors of dermal and epidermal (skin) growth. As such, it is a useful adjunct to wound care by increasing dermal and epidermal growth, including glycosaminoglycans, or GAGs (which bind to extracellular proteins like collagen, fibronectin, laminin, etc. and retain considerable amounts of water, thus preserving the skin structure) as well as the amount of collagen (a protein that helps skin heal) and decreasing the number of cells in mitosis (a type of cell division) (Rosenblum J, "Surface Acoustic Wave Patch Diathermy Generates Healing In Hard To Heal Wounds," European Wound Management Association 2011, for which we supplied devices which were precursors to WoundShield, but had no further involvement). In addition, the WoundShield instillation patch allows for administration of therapeutic agents into the wound area through a sonophoresis effect.

Many key processes in wound healing are dependent upon an adequate supply of oxygen. Diabetic foot ulcers are particularly in need of an adequate oxygen supply because the disease often results from poor perfusion (blood flow) and decreased oxygen tension. Oxygen is also important for the immune system to combat bacteria, synthesize collagen, help with fibroblast proliferation (fibroblasts are a type of cell that play a critical role in wound healing), form oxidative (taking place in the presence of oxygen) pathways for adenosine triphosphate, or ATP, formation (ATP transports chemical energy within cells for metabolism), and the nitric oxide dependent signaling pathways. It is generally believed that a lack of available oxygen is a basic contributing factor in the perpetuation of these wounds. Wound healing experts have developed a technique of perfusing ischemic wounds (which occur when blood flow is blocked) with hyper-oxygenated saline, while the wound is being treated with ultrasound, also known as sonication. This localized oxygenation therapy has many advantages over the use of hyperbaric chambers (large chambers in which the oxygen pressure is above normal), a common method for delivering oxygen to wounds, as it is more cost-effective, can be done at the patient's bedside and can be administered more frequently. The WoundShield instillation patch was tested as a potential ultrasound technology for this localized oxygen therapy. In one study (Morykwas M, "Oxygen Therapy with Surface Acoustic Waveform Sonication," European Wound Management Association 2011; we supplied devices for this study, but had no further involvement with it), oxygen sensors were placed in the wound bed to directly measure partial pressure of oxygen in an ischemic wound bed on a pig. The wound was perfused with hyperbaric oxygen and sonicated using the WoundShield instillation patch. With surface acoustic wave ultrasound technology, tissue oxygen levels (partial pressure of oxygen in the blood, or PaO2) were raised from a range of 20 mmHg (millimeters of mercury) to 60 mmHg in peripheral (periwound) areas, a 3 centimeter distance away from the transducer, and from 40 mmHg to greater than 100 mmHg in the central wound bed lying below the WoundShield instillation patch (see table below). The results of this study illustrated that the WoundShield instillation patch allowed oxygen to directly enter into the wound. The direct entry of the oxygen increased the amount of oxygen reaching the wound, which has been shown to advance the healing process. In addition, we believe that WoundShield's small size, lower cost and ease of use makes localized oxygen treatment commercially viable.



In 2012, results were published of a human feasibility trial for the WoundShield instillation patch that was performed at Duke University in North Carolina. Seven patients were treated with the WoundShield instillation patch for their wounds and average tissue oxygen levels (PaO2) increased by an average of 58% over baseline (Covington S, "Ultrasound-Mediated Oxygen Delivery to Lower Extremity Wounds," Wounds 2012; 24(8)). We supplied devices for this trial, but had no further involvement with it.

Market for Wound-Healing Devices

The global wound care device market totaled approximately $24 billion in 2015 and it is expected to grow at a CAGR of 6.7% during 2016-2022 (as reported by P&S Global Research in January 2017). According to the Global Report on Diabetes produced by the World Health Organization ("WHO") in 2016, globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. According to a report entitled "Advances in Wound Closure Technology" by Frost and Sullivan (2005), foot complexities are the most frequent causes for patients with diabetes to get hospitalized, with complications usually starting with the formation of skin ulcers. In addition, according to the American Burn Association, approximately 486,000 patients received medical treatment annually for burn injuries in 2016 in the United States. There are also policy-based factors that may increase the size of the wound care market. We anticipate that reimbursement decisions with respect to hospital acquired wounds may create a large market opportunity for wound care products, including WoundShield. Furthermore, in 2009, the Centers for Medicare and Medicaid Services announced that they would stop reimbursements for treatment of certain complications that they believed were preventable with proper care. One such complication was surgical site infections after certain elective procedures, including some orthopedic surgeries and bariatric surgery. We believe that such developments incentivize medical care providers to invest in reducing the risk of infection through the use of wound care products, including WoundShield.

Competition for WoundShield

The market for advanced wound care includes a number of competitors, such as Kinetic Concepts, Inc. (a subsidiary of the 3M Company), or KCI, Smith and Nephew plc and Convatec Inc., all of whom market wound-healing medical devices. Due to their size, in general these companies may have significant advantages over us. These competitors have their own distribution networks for their products, which gives them an advantage over us in reaching potential customers. In addition, they are vertically-integrated, which may allow them to maximize efficiencies that we cannot achieve with our third-party suppliers and distributors. Finally, because of their significantly greater resources, they could potentially choose to focus on research and development of technology similar to ours, more than we are able to. In general, we believe that these competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. However, we believe that our products differentiate us from these competitors, and we will be competitive on the basis of our technology. We believe that the strength of these competitors may create an opportunity through strategic partnerships.

At present, ultrasound treatment for wounds is limited only to wound debridement (removal of damaged tissue or foreign objects from a wound) and such products are marketed by Arobella Medical, LLC, which produces the Qoustic Wound Therapy System, Misonix Inc., which produces SonicOne products, and Alliqua Biomedical, Inc., which produces the MIST Therapy System. Due to their size, in general these companies may have the same advantages over us as discussed with respect to our competitors in the paragraph above. However, these ultrasound devices are indicated for use only in medical clinics and require an operator to deliver their treatment, thus limiting their use and application. The MIST Therapy System and Quostic Therapy System are a non-contact ultrasound device that delivers ultrasound through a mist that is applied directly on the wound.

We believe that these therapies are less advantageous than WoundShield because they require an operator to deliver the treatment and the removal of bandages to target the wound bed. In contrast, the WoundShield patch sits on normal skin bordering the open wound and no manipulation of the wound bandage is required. Moreover, WoundShield can be self-administered, without an operator, in both clinics and home settings. We also believe that WoundShield will prove to be an effective alternative to treating chronic wounds at a lower price than the existing products being used by medical practitioners. As such, we believe that facilities that are reimbursed based upon diagnosis-related groups will be more inclined to adopt WoundShield because it will provide the same therapeutic results at a significantly lower cost than traditional ultrasound therapies.

We are also aware of a small clinical study, for which results were reported in August 2013, in which a small ultrasound device showed positive results in the treatment of venous ulcers, a type of chronic wound. We understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that of the transducer's diameter. We believe our products would have certain other advantages over this potential device, if developed, including that our products weigh less and are thinner. However, given the early stage of development of this potential device, we cannot say with certainty how our products would compare.

The most common method of oxygen administration for wound healing is hyperbaric oxygen therapy, especially to treat specific ulcerations in diabetic patients. Hyperbaric oxygen therapy has been shown to increase vascular endothelial growth factor expression, which measures the creation of new blood vessels (Fok TC, at el, "Hyperbaric oxygen results in increased vascular endothelial growth factor (VEGF) protein expression in rabbit calvarial critical-sized defects", Schulich School of Medicine and Dentistry, University of Western Ontario, Canada). The activation of endothelial cells by VEGF sets in motion a series of steps toward the creation of new blood vessels (J Lewis et al, National Cancer Institute, Understanding Cancer and Related Topics, Understanding Angiogenesis). We believe that the WoundShield instillation patch, which can be used as an oxygen instillation system, will be complementary to, or in some cases an alternative to, the use of hyperbaric chamber therapy. This complementary treatment option will allow the treating physician greater therapeutic versatility in treating wounds. For a certain populace of patients, we believe that the WoundShield instillation patch could provide physicians with an alternative to hyperbaric oxygen therapy because it provides the same benefits as hyperbaric oxygen therapy at a lower cost to the patient. There are a number of competitors in the hyperbaric chamber therapy market, including approximately eight companies in the United States. Due to their size, in general these companies may have the same advantages over us discussed with respect to our competitors in the first paragraph of this section. However, we believe that the WoundShield instillation patch possesses certain advantages over the existing hyperbaric chamber therapy, including lower cost and greater ease of use. In addition, we believe that the WoundShield instillation patch will not necessarily compete with hyperbaric chamber therapy, but rather will often complement such therapy.

While we believe that WoundShield is well positioned to capture a share of the wound care market, WoundShield may be unable to achieve its anticipated place in the wound care market due to a number of factors, including, but not limited to, an inability to obtain the approval of the U.S. Food and Drug Administration, for which it is indicated and its failure to be adopted by health care practitioners and facilities or patients because of its status as a new product in a market that relies on patient-focused initiative to treat wounds.

Regulatory Strategy

For a general discussion of the U.S. Food and Drug Administration approval process with respect to our products, and regulation of our products in general, see "– Government Regulation" below.

Our general regulatory strategy for WoundShield has been focused on seeking U.S. Food and Drug Administration approval for a variety of indications. WoundShield obtained CE Mark approval in November 2012. Sanuwave has received the worldwide, exclusive rights to the Company's WoundShield product and technology. Accordingly, the Company does not expect to continue to directly engage in sales and marketing activities for the WoundShield technology and expects Sanuwave to undertake such activities.

Sales and Marketing

WoundShield has generated minimal revenues to date. In March 2020, we signed a license agreement with Sanuwave Health, Inc. for the manufacture and delivery of our WoundShield technology.

Clinical Trials

With respect to WoundShield, to date, we have conducted the following evaluation studies:

Purpose	Doctor/Location	Time, subjects	Objectives	Results
Clinical evaluation Physician initiated	Dr. J. Rosenblum, Shaare Zedek Medical Center	2008 8 patients	To evaluate novel technology on wound healing in diabetic foot ulcers.	Therapy showed significant changes in wound, wound size was reduced, patients felt less pain, necrotic tissue was less adhesive, necrotic tissue decreased in size. The duration of the trial was one week.
Clinical evaluation Physician initiated	Dr. J. Rosenblum, Shaare Zedek Medical Center	2010 8 patients	To evaluate novel technology on wound healing in diabetic foot ulcers.	The device, a precursor device to WoundShield using the same technology as WoundShield, had a positive effect on both epithelization of diabetic wounds and stimulating the precursors of dermal and epidermal growth. The duration of the trial was one week.
Clinical evaluation Physician initiated	Dr. S. Covington	2010 7 patients	The study aimed to determine if hyper oxygenated saline delivered by surface acoustic waves improves tissue oxygenation in lower extremity wounds.	Surface acoustic wave technology in conjunction with oxygenated saline can increase interstitial oxygen in wound bed. This trial to validate proof of concept was put on hold due to financial constraints. The duration of the trial was two weeks.

Third Party Reimbursement

NanoVibronix has entered into an agreement with Redemption Revenue Cycle Solutions LLC (“RRCS”), beginning on January 1, 2019. RRCS has an expertise in establishing reimbursement at a reasonable rate, and facilitating the billing for both NanoVibronix and its distributors. We have also retained McGuireWoods to assist in improving our PainShield 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, among others. 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 health care providers who use the products or therapies. Even though a new product may have been approved or cleared by the U.S. Food and Drug Administration 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 certain products, including ours.

One of the components in the reimbursement decision by most private insurers and governmental payers, including the Centers for Medicare and 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.

Obtaining reimbursement approval for a product from any government or other third -party payer is a time-consuming and costly process that could require us or our distributors to provide supporting scientific, clinical and cost-effectiveness data for the use of our product to each payer. Even if a code is obtained for a product, a third -party payer must still make coverage and payment determinations. When a payer determines that a product is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities. 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 health care industry to reduce the costs of products and services. In addition, health care 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.

UroShield. We expect these products to be used in inpatient settings and therefore reimbursed under the Diagnosis Related Group (DRG) or per diem reimbursement system. In addition, in an outpatient or home setting, we anticipate that these products will initially be purchased privately until a reimbursement code is obtained. However, we believe that if we can empirically demonstrate UroShield's efficacy in preventing recurrent hospitals admission in chronic Foley catheter patients and reducing overall per-patient cost, third party payers may accelerate the reimbursement approval process since the device could reduce their overall per-patient cost. We believe the natural progression of the adoption of this technology will allow for use in the home setting. We intend to pursue reimbursement in the Medicare Part B code to support the use for long term catheter use and infection prevention in the home.

PainShield. Effective as of January 2020, CMS approval for Medicare reimbursement was added through code K1004. The value of the reimbursement has not yet been confirmed.

WoundShield. We believe that the initial usage of these products will be in the hospital setting. Reimbursement in the hospital setting is typically governed by the DRG system, which is a prospective payment methodology that assigns a predetermined, fixed amount based on the patient's diagnoses. Such reimbursement will be sought by Sanuwave Health Inc. as the licensee of this technology.

New Product Under Development

Renooskin

In 2016, we started developing a device for the facial rejuvenation market called Renooskin. Previous in vitro studies on human skin were done showing that the SAW technology provided skin rejuvenation comparable to Retinol A which is a well-accepted anti-aging cream. We have developed a head band like applicator for the PainShield SAW treatment and are in the process of arranging for a pilot trial with a cosmetic dermatologist and/or plastic surgeon. We believe that, subject to proof of efficacy of the Renooskin and receiving regulatory approval, the device can be sold in a non-reimbursement market since cosmetic devices are private pay. We are still considering several paths towards commercialization.

Intellectual Property

Stemming from a combination of patent, copyright, trademark and trade secret laws, as well as non-disclosure agreements and other contracts, our intellectual property rights represent a vital resource to the management of our company. Therefore, we are continuing our practice of investing in obtaining appropriate legal protection for our innovations whenever possible. Moreover, we have begun adopting a more integrative approach to the management of our intellectual property that mutually aligns with our ongoing R&D strategies, commercial opportunities based on market analyses, and longer-term business objectives.

From our patented technologies to our trademarked brands, we believe our intellectual property has substantial value and has significantly contributed to our success to date.

Patents

We seek patent protection for our inventions not only to differentiate our products and technologies, but also to develop opportunities for licensing and secure our rights to profits therefrom.

Our patent portfolio includes at least the following issued patents, as well as a number of corresponding foreign patents in relevant jurisdictions: (1) U.S. Patent No. 7,393,501 to "*Method, Apparatus and System for Treating Biofilms Associated With Catheters"* (expiring on December 19, 2023); (2) U.S. Patent No. 7,829,029 to "*Acoustic Add-On Device for Biofilm Prevention in Urinary Catheter*" (expiring on October 27, 2025); (3) U.S. Patent No. 9,028,748 to "*System and Method for Surface Acoustic Wave Treatment of Medical Devices*" (expiring on July 11, 2030); and (4) U.S. Patent No. 9,585,977 directed to "*System and Method for Surface Acoustic Waves Treatment of Skin"* (expiring on August 20, 2033). These patents cover a wide range of embodiments and applications of our proprietary surface acoustic wave (SAW) technology, including our commercialized PAINSHIELD®, PAINSHIELD PLUS™, WOUNDSHIELD® and UROSHIELD® devices. Specifically, the patents provide for methods of generating SAW on surfaces of indwelling medical devices and to topical and urological applications therefor for alleviating pain, wound healing, and preventing formation of bacterial biofilms on catheters.

In addition to the rights afforded by the issued patents referenced above, on September 3, 2020, we filed U.S. Patent Application No. 17/025,969 directed to *"A Transdermal Patch of a Portable Ultrasound-Generating System for Improved Delivery of Therapeutic Agents and Associated Methods of Treatment."* This application covers applications of our existing technology to novel configurations of transdermal patches for improved transdermal administration of various therapeutic agents, including to the administration of therapeutically effective dosages of various drug products, including, but not limited to, *cannabis* products. Finally, on January 2, 2021, we filed Provisional Patent Application No. 63/134,956 directed to "*System and Methods for Treating Pain in a Subject by Targeted Application of Surface Acoustic Waves (SAW)."* This application covers embodiments relating to our most recently commercialized PainShield PLUS™ device. A non-provisional application for the above will be filed in the near future, but well before the January 2, 2022 due date.

We continue to develop and broaden our existing portfolio relating to our SAW technology platform and to possible new applications thereof. In addition, we have been exploring opportunities for other proprietary products in which our proprietary SAW technology could provide significant or improved therapeutic benefits.

We believe the granted patents and patent applications collectively cover our existing products to the extent necessary and may also be useful for protecting some of our future technology developments. To date, we are not aware of other companies that have patent rights to comparable systems and methods for surface acoustic wave treatment for skin.

We intend to continue patenting new technology as it is developed, and to actively pursue any infringement of any of our patents. As we continue to develop and broaden our existing portfolio, our primary focus is to explore potential new applications of our SAW technology. We are also exploring opportunities for other proprietary products in which our proprietary SAW technology could provide significant or improved therapeutic benefits.

Trademarks

In addition to patent protection, we own numerous registered trademarks for our commercialized WOUNDSHIELD® (in the U.S. and Canada), PAINSHIELD following, NanoVibronix® (in the U.S. and Canada), WOUNDSHIELD® (in the U.S. and Canada), PAINSHIELD®. (in the U.S. and Canada), and UROSHIELD® (in the U.S.). Generally, the protection afforded by trademarks is perpetual, subject to paying timely renewals and continuing proper use in commerce. In addition to the above, we expect to pursue additional trademark registrations to the extent we believe they would be beneficial and cost-effective.

Other Rights

We regularly enter into, and rely on, confidentiality and proprietary rights agreements with our employees, consultants, contractors and business partners to protect our trade secrets, proprietary technology and other confidential information. We control the use of our proprietary technology through relevant provisions, notifications, and disclaimers provided on our website, our customer terms of use, and our vendor terms and conditions.

Government Regulation

U.S. Food and Drug Administration Regulation

Each of our products must be approved, cleared by, or registered with the U.S. Food and Drug Administration before it is marketed in the United States. Before and after approval or clearance in the United States, our products, approved or cleared products and product candidates, are subject to extensive regulation by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. The U.S. Food and Drug Administration 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. PainShield has already obtained 510(k) marketing approval by the U.S. Food and Drug Administration.

In September 2020, the FDA exercised its Enforcement Discretion to allow distribution of the UroShield device in the United States. According to the FDA, "UroShield® device can use Intended Use Code (IUC) 081.006: Enforcement Discretion per final guidance, and FDA product code QMK (extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic)". Accordingly, the FDA's Enforcement Discretion clears the way for import of UroShield to the U.S. for limited use during the Covid-19 pandemic. The U.S. FDA may terminate or revoke this Enforcement Discretion at any time (after which the applicable products may no longer be used). The Enforcement Discretion does not ensure that UroShield will obtain 501(k) marketing approval.

U.S. Food and Drug Administration 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 U.S. Food and Drug Administration determines are necessary to reasonably ensure their safety and efficacy:

- Class I: general controls, such as labeling and adherence to quality system regulations, and a pre-market notification (510(k)) unless exempt;
- Class II: special controls, pre-market notification (510(k)) unless exempt, 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, or PMA, application.

WoundShield and PainShield are classified as Class II medical devices and require U.S. Food and Drug Administration authorization prior to marketing, by means of 510(k) clearance, except for our UroShield product, which we intend to seek clearance from the U.S. Food and Drug Administration through the de novo classification process, described below.

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 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 U.S. Food and Drug Administration issues a clearance letter finding substantial equivalence. The typical duration to receive 510(k) approval is approximately nine months from the date of the initial 510(k) submission, although there is no guaranty that the timing will not be longer.

The U.S. Food and Drug Administration may require us to perform clinical studies to show a product candidate's safety and efficacy in addition to technological equivalence in support of our filed 510(k). No matter which regulatory pathway we may take in the future towards marketing products in the United States, we believe we will be required to provide clinical proof of device effectiveness and safety.

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 U.S. Food and Drug Administration determines that the product does not qualify for 510(k) clearance, then a company must submit and the U.S. Food and Drug Administration must approve a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive nonclinical 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration determines the application or manufacturing facilities are not acceptable, the U.S. Food and Drug Administration may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the U.S. Food and Drug Administration ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, a U.S. Food and Drug Administration advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the U.S. Food and Drug Administration whether, or upon what conditions, the device should be approved. The U.S. Food and Drug Administration is not bound by the advisory panel decision. While the U.S. Food and Drug Administration often follows the panel's recommendation, there have been instances where the U.S. Food and Drug Administration has not. If the U.S. Food and Drug Administration 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. The typical duration to receive PMA approval is approximately two years from the date of submission of the initial PMA application, although there is no guarantee that the timing will not be longer.

As stated above, we anticipate that our UroShield product will receive a de novo review from the U.S. Food and Drug Administration. De novo review is a two-step process that requires a company to submit a 510(k) and complete a standard review, including an analysis of the risk to the patient and operator associated with the use of the device and the substantial equivalence rationale. Once that has been accomplished, and the medical device in question has been determined to be not substantially equivalent to another approved device, the product is automatically classified as a Class III device. The manufacturer can then submit a request for an evaluation to have the product reclassified from Class III into Class I or Class II. The U.S. Food and Drug Administration will review the device classification proposal and either recommend special controls to create a new Class I or II device classification or determine that the product is a Class III device. If the U.S. Food and Drug Administration determines that the level of risk associated with the use of the device is appropriate for a Class II or Class I designation, then the product can be cleared as a 510(k) and the U.S. Food and Drug Administration will issue a new classification regulation and product code. If the device is not approved through de novo review, then it must go through the standard PMA process for Class III devices.

Clinical Trials of Medical Devices

One or more clinical trials are generally required to support a PMA application and more recently are becoming necessary to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with U.S. Food and Drug Administration requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an investigational device exemption application to the U.S. Food and Drug Administration prior to initiation of the clinical study. An investigational device exemption 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 investigational device exemption will automatically become effective 30 days after receipt by the U.S. Food and Drug Administration unless the U.S. Food and Drug Administration notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board has approved the study.

During the study, the sponsor must comply with the U.S. Food and Drug Administration's investigational device exemption 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. The sponsor, the U.S. Food and Drug Administration, or the institutional review board 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 U.S. Food and Drug Administration typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

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 U.S. Food and Drug Administration quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;

- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and

- the Medical Device Reporting regulation, which requires reporting to the U.S. Food and Drug Administration of certain adverse experiences associated with use of the product.

Good Manufacturing Practices Requirements

Manufacturers of medical devices are required to comply with the good manufacturing practices set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act as further set forth in the Code of Federal Regulations as 21 CFR Part 820. Current good manufacturing practices ("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 an approved product must meet current good manufacturing practices requirements to the satisfaction of the U.S. Food and Drug Administration pursuant to a pre-PMA approval inspection before the facility can be used. Manufacturers, including third party contract manufacturers, are also subject to periodic inspections by the U.S. Food and Drug Administration and other authorities to assess compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer, and possibly us, 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration clearance, and requirements for licensing a product in a foreign country may differ significantly from U.S. Food and Drug Administration requirements.

The primary regulatory environment in Europe is the European Union, which consists of 27 member states and 32 competent authorities encompassing most of the major countries in Europe. In the European Union, the European Medicines Agency and the European Union Commission determined that PainShield, UroShield, and WoundShield are to be regulated as medical device products. These products are classified as Class II devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area. We are required to be recertified each year for CE by Intertek, which conducts an annual audit. The audit procedure, which includes on-site visits at our facility, requires us to provide Intertek with information and documentation concerning our management system and all applicable documents, policies, procedures, manuals, and other information.

The primary regulatory bodies and paths in Asia, Australia, and Latin America 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, requirements for quality management systems published by the International Organization of Standardization. In some countries outside Europe, we are or will be able to sell on the basis of our CE Mark. We have the Health for PainShield, WoundShield and UroShield, a certificate by the Israel Ministry of Health allowing us to sell PainShield, WoundShield and UroShield in Israel, a certificate allowing us to sell PainShield in Australia, and we are able to sell PainShield, WoundShield and UroShield in India and Ecuador based on our CE Mark. In addition, our distributor in Korea has applied for approval to sell PainShield and UroShield. We generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice, as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with good manufacturing practice 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.

U.S. Fraud and Abuse and Other Health Care Laws

In the United States, federal and state fraud and abuse laws prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of health care products and services. Other provisions of federal and state laws prohibit 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, other health care laws and regulations may apply, such as transparency and reporting requirements, and privacy and security requirements. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal and state health care programs. These laws are potentially applicable to manufacturers of products regulated by the U.S. Food and Drug Administration as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. The health care laws that may be applicable to our business or operations include:

- The federal Anti-Kickback Statute, which 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 health care program.

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which also impose obligations and requirements on health care providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information.

- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Manufacturing and Suppliers

In December 2018, we announced we appointed Quasar Engineering Ltd, as contract manufacturer for the PainShield®, UroShield® and WoundShield®, as well as other devices. Following our agreement with Sanuwave, Quasar is no longer the manufacturer of the WoundShield®. Quasar is a medical device manufacturer, located in China, with over 30 years of experience, serving major brands worldwide, with complex catheters, disposables, and U.S. Food and Drug Administration regulated assemblies. Starting in the fourth quarter of 2019, we started using Quasar to manufacture all of our newly redesigned products. Quasar temporarily shut down for sixty days in early 2020, due to the COVID-19 outbreak which lead to a significant delay in the production of goods needed to fulfill our sales orders, and became fully operational in April 2020. Presently, we are no longer experiencing delays in the production of our products.

We order certain component parts on an as-needed basis, generally from the manufacturer that provides us with the most competitive pricing. Our most significant suppliers for these components are APC International, Ltd., Rotel Product Engineering Ltd. and Sinpro Electronics Co., Ltd. We do not have written agreements with any of these suppliers, but we believe anyone could be easily replaced if necessary.

Customers

We currently sell our products both directly, through our website, and indirectly via distribution agreements, with approximately 93% of our sales coming through distributors in 2020. We expect that percentage to continue to grow as we enter into additional distribution agreements. We have exclusive and non-exclusive distribution agreements for our products with medical product distributors based in the United States, in the United Kingdom and various countries throughout Europe, India, Canada and Asia. Our two largest customers Ultra Pain Products Inc, and Protrade Sales Ltd constituted 60% of our revenues.

We are currently in discussions with several distribution companies with access to various markets in the United States, Europe, and Asia, as well as Veterans Administration facilities. Our current agreements stipulate that distributors will be responsible for carrying out local marketing activities and sales. We are responsible for training, providing marketing guidance, marketing materials, and technical guidance. In addition, in most cases, all sales costs, including sales representatives, incentive programs, and marketing trials, will be borne by the distributor. We expect any future distribution agreements to contain substantially similar stipulations. Under our current agreements, distributors purchase our products from us at a fixed price. Our current agreements with distributors are generally for a term of approximately two to three years and automatically renew for an additional annual terms unless modified by either party.

Employees

Our People and Human Capital Resources

Employees

As of December 31, 2020, we had 11 full-time employees and one part-time employee, up from 10 employees as of December 31, 2019, and as of March 15, 2021, we have added one additional full-time employee in 2021. We also regularly work with several independent consultants and other contract organizations to support our business and we regularly evaluate additional talent to help support our product manufacturing, development, financial, and other capabilities.

Diversity and Inclusion

We believe that an inclusive culture is required to understand and develop products that benefit all patients. By embracing differences, we aim to foster an environment of respect and trust in an effort to facilitate creativity, spark passion, and help us achieve better outcomes for all those who work at the Company. We are committed to creating and maintaining a workplace free from discrimination or harassment, including on the basis of any class protected by applicable law, and our recruitment, hiring, development, training, compensation, and advancement practices are based on qualifications, performance, skills, and experience without regard to gender, race, or ethnicity. Our management team and employees are expected to exhibit and promote honest, ethical, and respectful conduct in the workplace, including adhering to the standards for appropriate behavior set forth in our code of conduct.

Compensation and Benefits

We operate in a highly competitive environment for human capital, particularly as we seek to attract and retain talent with relevant experience in the medical device sector. Therefore, we strive to provide a total rewards package to our employees that is competitive with our peer companies, including competitive healthcare benefits and in certain cases, stock options. We also offer paid leave as mandated by government regulations, flexible work schedules, and other benefits as mandated by government regulations.

We also offer key employees the benefit of equity ownership in Nanovibronix through stock option grants. We believe these grants both help promote alignment between our employees and our stockholders and provide retention benefits, as the awards generally vest over a three-year period.

We do not have any employees that are represented by a labor union or that have entered into a collective bargaining agreement with the Company.

Safety, Wellness, and Our Response to COVID-19

At Nanovibronix, we believe that health matters to everyone, and the safety health, and wellness of our employees is one of our top priorities. We are committed to developing and fostering a work environment that is safe, professional, and promotes teamwork, diversity, and trust in order to afford all of our employees the opportunity to contribute to the best of their abilities.

During 2020, in response to the COVID-19 pandemic, we took certain measures and responded to changes in our operational needs, including actions designed to provide a safe work environment for our employees. These actions included investing in technology solutions to support increased work-from-home capabilities, shifting work schedules to reduce the number of people present in our offices, requiring mask wearing and social distancing, making hand sanitizer readily available, and other measures intended to comply with health and safety protocols as required by federal, state, and local governmental agencies, as well as guidance from the U.S. Centers for Disease Control and Prevention and similar public health authorities

Available Information

The Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments thereto, are filed with the SEC. The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and files or furnishes reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on the Company's website at nanovibronix.com, as soon as reasonably practicable after we have electronically filed with, or furnished to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the Company's references to website URLs are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We have a history of losses and we expect to continue to incur losses and may not achieve or maintain profitability.

For the fiscal year ended December 31, 2020 we had a net loss of approximately $4.3 million, with revenues of approximately $623,000. As of December 31, 2020, we had an accumulated deficit of approximately $42.7 million. We expect to incur losses for at least the next year, as we continue to incur expenses related to seeking U.S. Food and Drug Administration approval for UroShield, and market acceptance of PainShield, which will require costly additional clinical trials and research, further product development and professional fees associated with regulatory compliance. Even if we succeed in commercializing our new products, we may not be able to generate sufficient revenues to cover our expenses and achieve profitability or be able to maintain profitability.

The recent coronavirus outbreak may adversely affect our business.

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China, and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China and other affected countries. The ongoing COVID-19 pandemic has and may continue to adversely impact our business, as our operations are based in and rely on third parties located in countries affected by the pandemic. Our third-party manufacturer, which is based in China, temporarily shut down for sixty days during 2020 due to the pandemic and became fully operational in April 2020 which led to a significant delay in the production of goods needed to fulfill our sales orders which were scheduled to be fulfilled in our first quarter of 2020. We were able to fulfill these orders in the second quarter of 2020. Additionally, the notified regulatory body we rely on to obtain European CE approval is located in Italy and was shut down for approximately six weeks from March to April 2020, which delayed our submission for CE mark approval for the year 2020. The CE Mark approval was subsequently approved in April 2020. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 have had and may continue to have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The financial downturn has compelled us to furlough or reduce working hours for much of our operating staff, and has forced remaining staff as well as third-party contractors, to work remotely. In addition, many staff members continue to operate remotely from their homes, which is continuing to result in delays in obtaining certain financial records. We also rely on third-party professionals to provide services such as the preparation of our financial statements and to conduct audits, and many of these parties have been affected by government-imposed precautionary measures, thereby delaying our receipt of these services. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases. Therefore, the COVID-19 pandemic has and may again disrupt production and cause delays in the development, supply and delivery of our products, our operation, further divert the attention and efforts of the medical community coping with COVID-19 and disrupt the marketplace in which we operate. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, its variants and the actions to contain COVID-19 or treat its impact, among others. The COVID-19 pandemic could continue to materially disrupt our business and operations, hamper our ability to raise additional funds or sell or securities, continue to slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations.

If we are unable to raise additional capital, our clinical trials and product development will be limited and our long-term viability will 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 of the sale of our securities, with only limited revenue being generated from our product sales. In order to fully realize our business objectives, we may need to raise additional capital. We will seek to raise such additional funds 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 through the imposition of restrictive covenants and requiring us to pledge assets in order to secure repayment. In addition, if we raise funds through the sale of equity, we may issue equity securities with rights superior to our common stock, including voting rights, rights to proceeds upon our liquidation or sale, rights to dividends and rights to appoint board members. There can be no assurance that we will be able to complete a required financing on acceptable terms or at all. If such financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities. 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 the timing and amount of any required financings, including, without limitation:

- unforeseen developments during our clinical trials;
- delays in our receipt of required regulatory approvals;
- delayed market acceptance of our products;
- unanticipated expenditures in our acquisition and defense of intellectual property rights, and/or the loss of those rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- unforeseen changes in healthcare reimbursement for any of our approved products;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- 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;
- enactment of new legislation or administrative regulations;
- the application to our business of new regulatory interpretations;
- claims that might be brought in excess of our insurance coverage;
- the failure to comply with regulatory guidelines; and
- the uncertainty in industry demand;
- the delisting of our common stock from the NASDAQ Capital Market; and
- the geographic, social and economic impact of COVID-19 on the Company’s business operations.

Any required financing efforts may divert our management from their day-to-day activities, which may adversely affect its ability to develop and commercialize our products Moreover, if we complete additional financing by issuing equity securities, the percentage ownership of its existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders.

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

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 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 reimbursement or pricing approvals in markets we seek to enter in a timely manner, if at all. Our failure to receive reimbursement or pricing approvals in target markets would negatively impact market acceptance of our products in these jurisdictions, placing us at a material cost disadvantage to our competitors.

Even if we obtain reimbursement approvals for our products, 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 policies of third party payers that limit reimbursement may adversely affect the demand for our products currently under development and 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.

In the United States, specifically, health care providers, such as hospitals and clinics, and individual patients, generally rely on third-party payers. Third-party reimbursement is dependent upon decisions by the Centers for Medicare and Medicaid Services, contracted Medicare carriers or intermediaries, individual managed care organizations, private insurers, other governmental health programs and other payers of health care costs. Failure to receive or maintain favorable coding, coverage and reimbursement determinations for our products by these organizations could discourage medical practitioners from using or prescribing our products due to their costs. In addition, with recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform including the reform of the Medicare and Medicaid programs, and on the cost of medical products and services, which could limit reimbursement. Additionally, third-party payers are increasingly challenging the prices charged for medical products and services, and imposing conditions on payment. We may be unable to sell our products on a profitable basis if third-party payers deny coverage, provide low reimbursement rates or reduce their current levels of reimbursement.

The medical device and therapeutic product industries are highly competitive and subject to rapid technological change. If our competitors are 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 companies, such as Neurometrix Inc., Zetrox, Kinetic Concepts, Inc., (a subsidiary of the 3M Company) and Smith & Nephew plc, manufacturers of certain portable ultrasound devices capable of self-administered use, as well as from academic institutions, government agencies, and private and public research institutions in the United States and abroad. Most, if not all, 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, marketing approved products, protecting and defending their intellectual property rights and designing around the intellectual property rights of others. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements, or mergers with, or acquisitions by, large and established companies, or through the development of novel products and technologies.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may be able to respond to changes in technology or the marketplace faster than us. Our competitors may develop and commercialize medical devices that are safer or more effective 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. Given our small size and lack of resources, we are often at a disadvantage with our competitors in all of these areas, which could limit or eliminate our commercial opportunities.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of medical devices and products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. We currently carry clinical trial and product liability insurance for the products we sell. However, we cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of additional commercial products as we obtain marketing approval for our product candidates in development and as our sales expand, but we may be unable to obtain commercially reasonable product liability insurance for such products. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims and we continue to make sales, or if our coverages turns out to be insufficient, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could reduce our value or marketability.

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 the risks that:

- the U.S. Food and Drug Administration 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;
- 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.

Additionally, we currently have limited experience in marketing or selling our products, and we have a limited marketing and sales staff and distribution capabilities. Developing a marketing and sales force is time-consuming and will involve the investment of significant amounts of financial and management resources, and could delay the launch of new products or expansion of existing product sales. In addition, we compete with many companies that currently have extensive and well-funded marketing and sales operations. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our ability to generate revenues will suffer.

Furthermore, even if we enter into marketing and distributing arrangements with third parties, we may have limited or no control over the sales, marketing and distribution activities of these third parties, and these third parties may not be successful or effective in selling and marketing our products. If we fail to create successful and effective marketing and distribution channels, our ability to generate revenue and achieve our anticipated growth could be adversely affected. If these distributors experience financial or other difficulties, sales of our products could be reduced, and our business, financial condition and results of operations could be harmed.

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.

If we fail to retain our key management, or to attract and keep additional key personnel, we may be unable to successfully execute our business plan.

Our success depends on our ability to attract, retain and motivate highly qualified management and personnel. As a small company with ten full-time employees and four contract employees, our success depends on the continuing contributions of our management team and qualified personnel and on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other 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. We are also at a disadvantage in recruiting and retaining key personnel as our small size and limited resources may be viewed as providing a less stable environment, with fewer opportunities than would be the case at one of our larger competitors. 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. In addition, the replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

Our need to increase the size of our organization and may not successfully manage our growth.

We are a clinical-stage company with a small number of planned employees, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve its operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance its operational, financial and management systems in conjunction with its potential future growth, such failure could have a material adverse effect on our business, financial condition and results of operations.

Our failure to protect our intellectual property rights could diminish the value of our solutions, weaken our competitive position and reduce our revenue.

We regard the protection of our intellectual property, which includes patents and patent applications, trade secrets, trademarks and domain names, as critical to our success. We strive to protect our intellectual property rights by relying on federal, state and common law rights, as well as contractual restrictions. We enter into confidentiality and invention assignment agreements with our employees, consultants and contractors, and confidentiality agreements with parties with whom we conduct business in order to limit access to, and disclosure and use of, our proprietary information. However, these contractual arrangements and the other steps we have taken to protect our intellectual property may not prevent the misappropriation of our proprietary information or deter independent development of similar technologies by others.

We have obtained patents and we have patent applications pending in both the United States and foreign jurisdictions. There can be no assurance that our patent applications will be approved, that any patents issued will adequately protect our intellectual property, or that these patents will not be challenged by third parties or found to be invalid or unenforceable. We have also obtained trademark registration in the United States and in foreign jurisdictions. Effective trade secret, trademark and patent protection is expensive to develop and maintain, both in terms of initial and ongoing registration requirements and the costs of defending our rights. We may be required to protect our intellectual property in an increasing number of jurisdictions, a process that is expensive and may not be successful or which we may not pursue in every location. We may, over time, increase our investment in protecting our intellectual property through additional patent filings that could be expensive and time-consuming.

Monitoring unauthorized use of our intellectual property is difficult and costly. Our efforts to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Further, our competitors may independently develop technologies that are similar to ours but which avoid the scope of our intellectual property rights. Further, the laws in the United States and elsewhere change rapidly, and any future changes could adversely affect us and our intellectual property. Our failure to meaningfully protect our intellectual property could result in competitors offering solutions that incorporate our most technologically advanced features, which could seriously reduce demand for our products. In addition, we may in the future need to initiate infringement claims or litigation. Litigation, whether we are a plaintiff or a defendant, can be expensive, time-consuming and may divert the efforts of our technical staff and managerial personnel, which could harm our business, whether or not the litigation results in a determination that is unfavorable to us. In addition, litigation is inherently uncertain, and thus we may not be able to stop our competitors from infringing our intellectual property rights.

We could incur substantial costs and disruption to our business as a result of any dispute related to, or claim of infringement of another party's intellectual property rights, which could harm our business and operating results.

In recent years, there has been significant litigation in the United States over patents and other intellectual property rights. From time to time, we may face allegations that we or customers who use our products have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including allegations made by our competitors or by non-practicing entities, or that we or our customers have misappropriated the intellectual property rights of such third parties. We cannot predict whether assertions of third party intellectual property rights or claims arising from these assertions will substantially harm our business and operating results. If we are forced to defend any infringement or misappropriation claims or attacks on the validity of our intellectual property rights, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. Most of our competitors have substantially greater resources than we do and are able to sustain the cost of complex intellectual property litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us, among other things: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to redesign our products; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all. In any event, we may need to license intellectual property which would require us to pay royalties or make one-time payments. Even if these matters do not result in litigation or are resolved in our favor or without significant cash settlements, the time and resources necessary to resolve them could harm our business, operating results, financial condition and reputation.

We face risks associated with litigation and claims.

We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, fraud and abuse, personal injury and product liability matters.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business.

Risks Related to the Regulation of Our Products

We are subject to extensive governmental regulation, including the requirement of U.S. Food and Drug Administration approval or clearance, before our product candidates may be marketed.

The process of obtaining U.S. Food and Drug Administration approval is lengthy, expensive and uncertain, and we cannot be sure that our additional product candidates will be approved in a timely fashion, or at all. If the U.S. Food and Drug Administration 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.

Both before and after approval or clearance of our product candidates, we, 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:

- FDA issuance of Form 483 or Warning Letters, which may be made public and may lead to further regulatory or enforcement actions, or similar letters by other regulatory authorities;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in U.S. Food and Drug Administration approval and clearance, or U.S. Food and Drug Administration refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunction or other restrictions imposed on our operations, including closing our facilities or our contract manufacturers' facilities; or
- criminal prosecutions.

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

- testing and quality control;
- manufacturing;
- quality assurance

- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the U.S. Food and Drug Administration will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct.

The U.S. Food and Drug Administration's requirements may change and additional government 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.

The UroShield has not been cleared or approved by the U.S. FDA, nor has it undergone the same type of review as an FDA-approved or cleared device.

In September 2020, the U.S. FDA exercised its Enforcement Discretion to allow distribution of our UroShield device in the United States. This temporary authorization is limited to use as an extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic. The U.S. FDA may terminate or revoke this enforcement discretion policy at any time (after which the applicable products may no longer be used). There is no guarantee that our collaborators or customers will purchase or use the UroShield, that any sales of UroShield by us will generate any revenue or profits, or that we will ever be successful in obtaining U.S. FDA clearance or approval for the UroShield.

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 where we do not already possess regulatory approval 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, as well as reimbursement and healthcare payment systems. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. We may be required to perform additional pre-clinical, clinical or post-approval studies even if U.S. Food and Drug Administration approval has been obtained. 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.

We are uncertain regarding the success of our clinical trials for our products in development.

We believe that all of our products in development, which currently consists of only RenooSkin, will require clinical trials to determine their safety and efficacy by regulatory bodies in their target markets, including the U.S. Food and Drug Administration and various foreign regulators. There can be no assurance that we will be able to successfully complete the U.S. and foreign regulatory approval processes for products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate our products to be safe and efficacious.

We depend on Sanuwave Health, Inc. (Sanuwave) for developing and commercializing our WoundShield technology.

In March 2020, we entered into a license agreement with Sanuwave for the manufacture and delivery of our WoundShield technology. Under this agreement, Sanuwave has received the worldwide, exclusive rights to our WoundShield technology. Sanuwave will bear the cost and clinical validation responsibilities associated with obtaining approval for WoundShield from the FDA and other regulatory agencies around the world. Sanuwave is also responsible for manufacturing and commercializing the WoundShield product and technology. Our right to receive a milestone payment under the license agreement depends on the achievement of FDA approval by Sanuwave and our ability to receive royalties under the agreement depends on Sanuwave's successful commercialization of the WoundShield product and technology.

The development and commercialization of the WoundShield product and technology and our ability to receive a potential milestone and royalty payments under the license agreement with Sanuwave, could be adversely affected if Sanuwave:

- lacks or does not devote sufficient time and resources to the development and commercialization of the WoundShield product and technology;
- lacks or does not devote sufficient capital to fund the development and commercialization of the WoundShield product and technology;
- develops, either alone or with others, products that compete with the WoundShield product and technology;
- fails to gain the requisite regulatory approvals for the WoundShield product and technology;
- does not successfully commercialize the WoundShield product and technology;
- does not conduct its activities in a timely manner;
- terminates its license with us; or
- does not effectively pursue and enforce intellectual property rights relating to the WoundShield product and technology.

We have limited or no control over the occurrence of any of the foregoing. Furthermore, disagreements with Sanuwave could lead to disputes, which could be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization milestone and royalties based on further development and sales of the WoundShield product and technology.

Healthcare reform measures could adversely affect our business and financial results.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may adversely affect our business and financial results. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. For example, the Patient Protection and Affordable Act of 2010, commonly referred to as the Affordable Care Act, contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance and delaying the implementation of certain fees mandated by the Affordable Care Act. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and negatively affect our business, financial condition and results of operations.

The current presidential administration and Congress may pursue significant changes to the current healthcare laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on our industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may negatively affect our business, financial condition and results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may negatively affect our business, financial condition and results of operations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products.

Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

If we fail to comply with the U.S. federal and state fraud and abuse and other health care laws and regulations, 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.

All of our financial relationships with health care providers and others who provide products or services to federal health care program beneficiaries are potentially governed by the federal and state fraud and abuse laws, and other health care laws and regulations may be or become applicable to our business and operations and expose us to risk. For example:

- The federal Anti-Kickback Statute, which 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 health care program.

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which also impose obligations and requirements on health care providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information.

- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. Efforts to ensure that our business arrangements with third parties and our operations are compliant with applicable health care laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. If we are found to be in violation of any current or future statutes or regulations involving applicable fraud and abuse or other health care laws and regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded health care programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, which could have a material adverse effect on our business, results of operations and financial condition. If any physicians or other health care providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs, which could adversely affect our ability to operate our business and our results of operations.

Risks Related to our Operations in Israel

We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.

Our principal offices and manufacturing facilities are located in Israel and most of our officers and employees are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. Civil unrest and political turbulence has occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. The civil war that has been ongoing in Syria has escalated, and this instability and any intervention may lead to additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran also has a strong influence among extremist groups in the region. These situations may potentially escalate in the future to more violent events which may affect Israel and our operations. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Our operations could be disrupted by the absence of a significant number of our employees. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

We expect our revenues from future licensing agreements to be denominated mainly in U.S. dollars or in Euros. We pay a substantial portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of the employees in Israel and payment to part of the service providers in Israel and other territories, are paid in New Israeli Shekels, or NIS, and in other currencies. In addition, a portion of our financial assets is held in NIS and in other currencies. As a result, we are exposed to the currency fluctuation risks, and we do not attempt to hedge against such risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher than anticipated. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

It may be difficult for investors in the United States to enforce any judgments obtained against us or any of our directors or officers.

Almost all of our assets are located outside the United States, although we do maintain a permanent place of business within the United States. In addition, some of our officers and directors are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons' assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. directors or officers, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

Risks Related to Our Organization and Our Securities

We are seeking stockholder ratification of an increase in the number of authorized shares of common stock and the issuance of such shares pursuant to Section 204 of the DGCL.

On December 4, 2020, certain holders of our Series C Convertible Preferred Stock ("Series C Preferred Stock") converted 396,509 shares of Series C Preferred Stock into shares of our common stock, resulting in an overissue of 246,523 shares of our common stock in excess of the number of authorized shares of our common stock. In December 2020 and January 2021, certain holders of warrants we had issued in December 2020 (the "December 2020 Warrants") exercised a portion of the December 2020 Warrants resulting in an additional overissue of 2,657,144 shares of our common stock. On January 22, 2021, a holder of warrants we previously issued in various offerings (the "Pre-Existing Warrants") exercised a portion of the Pre-Existing Warrants resulting in an additional overissue of 1,205,968 shares of our common stock for a total over-issuance of 4,109,635 shares of our common stock.

Our Board, in consultation with counsel, determined that it is in the best interests of the Company and our stockholders to ratify, pursuant to Section 204 of the Delaware General Corporation Law ("DGCL") and Delaware common law, an increase in the number of authorized shares of our common stock from 20,000,000 to 24,109,635 (the "Authorized Share Increase") and the issuance of 4,109,635 shares of common stock (the "Authorized Share Increase Issuance") upon conversion of the Series C Preferred Stock and the exercise of certain December 2020 Warrants and Pre-Existing Warrants (the "Share Increase Ratification"). On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders (the "Special Meeting") to be held at 10:00 a.m. Eastern time on March 31, 2021 to (i) ratify the Authorized Share Increase and the Authorized Share Increase Issuance, and (ii) further increase the number of our authorized shares of common stock. On March 31, 2021, we did not have the requisite vote to approve the Share Increase Ratification and adjourned the Special Meeting until 10:00 a.m. Eastern time on April 14, 2021 in an effort to obtain additional votes. At the reconvened Special Meeting on April 14, 2021, we again did not have the requisite vote to approve the Share Increase Ratification and further adjourned the Special Meeting until 10:00 a.m. Eastern time on April 27, 2021. Although we have adjourned the Special Meeting in an effort to secure the necessary stockholder approval, there can be no assurance that we will receive the necessary stockholder approval for the Share Increase Ratification. If we do not secure the necessary stockholder approval, we will need to explore other legal options for approval of the Share Increase Ratification.

The failure to approve the Share Increase Ratification may leave us exposed to potential claims that (i) the past issuances of our common stock since December 4, 2020 may not be valid; (ii) the Company does not have sufficient authorized but unissued shares of common stock to permit future sales and issuances of common stock, including pursuant to outstanding shares of preferred stock, warrants and equity awards; and (iii) we would not be able to validate our total outstanding shares of common stock in connection with any strategic transaction that our Board may determine is advisable, including, without limitation, a sale of the Company, a business combination or merger, or a license or other disposition of corporate assets of the Company. Any inability to issue common stock in the future and any invalidity of past issuances of Common Stock could expose us to significant claims and have a material adverse effect on our liquidity, which could result in our filing for bankruptcy or an involuntary petition for bankruptcy being filed against us.

If we do secure stockholder approval of the Share Increase Ratification, we will file a Certificate of Validation with the Secretary of State of the State of Delaware. Even if we filed the Certificate of Validation, any claim that (i) the increase in the number of authorized shares of common stock and related issuance of such shares ratified pursuant to the Share Increase Ratification is void or voidable due to a failure of authorization, or (ii) the Delaware Court of Chancery should declare in its discretion that the Share Increase Ratification not be effective or be effective only on certain conditions (collectively, the "Subsequent Claims") may still be brought within 120 days from the time that the filing of the Certificate of Validation with the Secretary of State of the State of Delaware becomes effective in accordance with the Delaware General Corporation Law. We can provide no assurance that Subsequent Claims will not be made within the available time period for making such claims.

The price of our securities may be volatile, and the market price of our securities may drop below the price you pay.

We expect that the price of our securities will fluctuate significantly. Market prices for securities of early-stage medical device companies have historically been particularly volatile. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- progress, or lack of progress, in developing and commercializing our products;
- favorable or unfavorable decisions about our products or intellectual property from government regulators, insurance companies or other third-party payers;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled "Risk Factors"; and
- general market and economic conditions.

In recent years, the stock markets, in general, have experienced extreme price and volume fluctuations especially in the biotechnology sector. Broad market and industry factors may materially harm the market price of shares of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against that company. If we were involved in any similar litigation, we could incur substantial costs and our management's attention and resources could be diverted. On March 12, 2020, the WHO declared COVID-19 to be a pandemic, and the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common shares.

We have a significant number of warrants and options, and future sales of our common stock upon exercise of these options or warrants, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Our stockholders and the holders of our outstanding warrants and options, upon exercise of these options or warrants, may sell substantial amounts of our common stock in the public market. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

In addition, the fact that our stockholders and holders of our warrants and options can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Although our shares of common stock are listed on the NASDAQ Capital Market, we currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.

Although our shares of common stock are listed on the NASDAQ Capital Market under the symbol "NAOV," trading volume in our common stock has been limited and an active trading market for our shares of common stock may never develop or be maintained. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered.

If we fail to comply with the continued listing requirements of the NASDAQ Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on the NASDAQ Capital Market. We must satisfy NASDAQ's continued listing requirements, including, among other things, a minimum stockholders' equity of $2.5 million and a minimum closing bid price of $1.00 per share or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from the NASDAQ Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

On August 5, 2020, the Company received notice from the Listing Qualifications Staff of Nasdaq indicating that the Company no longer satisfied the Nasdaq Listing Rule 5550(b)(1) (the "Rule"), which requires listed companies to maintain stockholders' equity of at least $2.5 million for continued listing on Nasdaq, and was therefore subject to delisting. On November 5, 2020, the Company received a subsequent letter from the Nasdaq indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between September 24, 2020 through November 4, 2020, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 555(a)(2). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until May 4, 2021 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

On February 3, 2021, the Company announced that it had received two notices from Nasdaq indicating that it had regained compliance with the equity requirement and the minimum bid price requirement and therefore it was no longer subject to a pending delisting.

There is no assurance that we can maintain in compliance with such minimum listing requirements. If our common stock were delisted from NASDAQ, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

If we fail to maintain effective internal control over financial reporting,* our business, financial condition or results of operations *may be adversely affected.

As a public reporting company, we are required to establish and maintain effective internal control over financial reporting. Failure to establish such internal control, or any failure of such internal control once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. Any failure of our internal control over financial reporting could also prevent us from maintaining accurate accounting records and discovering accounting errors and financial frauds.

Rules adopted by the Securities and Exchange Commission pursuant to Section 404 of Sarbanes-Oxley Act of 2002 require annual assessment of our internal control over financial reporting. The standards that must be met for management to assess the internal control over financial reporting as effective are complex, and require significant documentation, testing and possible remediation to meet the detailed standards. We may encounter problems or delays in completing activities necessary to make an assessment of our internal control over financial reporting. If we cannot assess our internal control over financial reporting as effective, investor confidence and share value may be negatively impacted. In addition, management's assessment of internal control over financial reporting may identify weaknesses and conditions that need to be addressed in our internal control over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting (including those weaknesses identified in our periodic reports), or disclosure of management's assessment of our internal control over financial reporting may have an adverse impact on the price of our securities.

As disclosed in Part II, Item 9A, “Controls and Procedures,” we have identified material weaknesses in our internal control over financial reporting due to a lack of a full and complete testing of our disclosure controls and procedures and separately related to the recent overissuance of shares of our common stock. We concluded that our internal control over financial reporting and related disclosure controls and procedures were not effective as of December 31, 2020. Our management has implemented remediation measures with respect to the controls and written policies and procedures as described in Part II, Item 9A, “Controls and Procedures,” and management expects that such measures will be sufficient to fully remediate such material weaknesses in our internal control over financial reporting that existed as of December 31, 2020. However, we have not implemented remediation measures with respect to the overissuance of shares of our common stock but expect to have a plan of remediation in place during the second quarter of 2021. We are also seeking a ratification from our stockholders with respect to the overissuance of shares of our common stock . We cannot guarantee that these steps will be sufficient to remediate the deficiencies or that we will not have a material weakness in the future. If our remedial measures are insufficient to address the material weakness or if additional material weaknesses arise in the future, our interim or annual financial statements may contain material misstatements or omissions and we could be required to restate our financial results.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to our filing status will make our common stock less attractive to investors.

We are a “smaller reporting company” and, thus, have certain decreased disclosure obligations in our SEC filings, including, among other things, simplified executive compensation disclosures and only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as a “smaller reporting company” may make it harder for investors to analyze our results of operations and financial prospects and may make our common stock a less attractive investment. If some investors find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our securities, thereby depressing the market price of our securities. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- allow the authorized number of directors to be changed only by resolution of our board of directors;

- authorize our board of directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholder meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law that may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, the price of our securities and their trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. Currently there is only one research coverage by a securities and industry analyst. If one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our securities and their trading volume to decline.

We may be subject to ongoing restrictions related to grants from the Israeli Office of the Chief Scientist.

Through our Israeli subsidiary, as of December 31, 2017, we received grants of $437,000 from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the Office of the Chief Scientist, for research and development programs related to products that we are not currently commercializing or marketing. Because we are no longer developing the product to which the grants relate, we do not believe that we are subject to any material conditions with respect to the grants, except for the restrictions on our ability to make certain transfers of the technology or intellectual property related to these grants described below. We could in the future determine to apply for further grants. If we receive any such grants, we would have to comply with specified conditions, including paying royalties with respect to grants received. If we fail to comply with these conditions in the future, sanctions might be imposed on us, such as grants could be cancelled and we could be required to refund any payments previously received under these programs.

Pursuant to the Israeli Encouragement of Industrial Research and Development Law, any products developed with grants from the Office of the Chief Scientist are required to be manufactured in Israel and certain payments may be required in connection with the change of control of the grant recipient and the financing, mortgaging, production, exportation, licensing and transfer or sale of its technology and intellectual property to third parties, which will require the Office of the Chief Scientist's prior consent and, in case such a third party is outside of Israel, extended royalties and/or other fees. This could have a material adverse effect on and significant cash flow consequences to us if, and when, any technologies, intellectual property or manufacturing rights are exported, transferred or licensed to third parties outside Israel. If the Office of the Chief Scientist does not wish to give its consent in any required situation or transaction, we would need to negotiate a resolution with the Office of the Chief Scientist. In any event, such a transaction, assuming it was approved by the Office of the Chief Scientist, would involve monetary payments, such as royalties or fees, of not less than the applicable funding received from the Office of the Chief Scientist plus interest, not to exceed, in aggregate, six times the applicable funding received from the Office of the Chief Scientist.

Because we do not expect to pay cash dividends for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 and 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We lease an office and manufacturing facility in Nesher, Israel and maintain an office in Tyler, Texas. Our lease for the facility in Nesher expires on June 30, 2021. The space is approximately 160 square meters. We pay approximately $3,600 per month under our lease. We also use a facility in Tyler, Texas from an unrelated party, for which we pay rent of $1,200 a month although we do not have a lease. This space is approximately 200 square meters. We believe that our facilities are adequate to meet our current and proposed needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in certain claims and litigation arising out of the ordinary course and conduct of business. Management assesses such claims and, if it considers that it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated, provisions for loss are made based on management's assessment of the most likely outcome.

See "Item 8. Financial Statements and Supplementary Data – Note 13. Commitments and Contingencies," which information is incorporated herein by reference, for a description of pending and recent litigation.

On December 17, 2019, a lawsuit was filed by a former officer and director, Jona Zumeris, in the Haifa Israel District Financial Court, seeking damages of approximately $900,000 for breach of the Separation Agreement executed on July 4, 2018. The Israeli court issued a court order demanding that we restrict approximately $700,000 of the Company's money until the matter is adjudicated. The Company appealed the court order and in February 2020, the Company agreed to restrict approximately 1,187,000 NIS ("New Israeli Shekel") and agreed to try to settle the matter in mediation. On November 30, 2020, the Company funded the escrow account with $391,000. In January 2021, the parties reached a settlement in which the Company paid the plaintiff approximately $366,000 as settlement in full.

On February 26, 2021, Protrade Systems, Inc. ("Protrade") filed a Request for Arbitration (the "Request") with the International Court of Arbitration (the "ICA") of the International Chamber of Commerce alleging the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $3 million. The Company disputes the claims asserted by Protrade and intends to respond to the Request and defend against the claims vigorously.

Except as referenced above, there are no other material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder of more than 5% of our common stock, or any associate of any of the foregoing is an adverse party or has a material interest adverse to our interest.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock has been quoted on the NASDAQ Capital Market under the symbol "NAOV" since November 8, 2017. Prior to that date, our common stock had been quoted on the OTCQB over-the-counter marketplace under the symbol "NAOV" since April 10, 2015. Prior to April 10, 2015, there was no established public trading market for our common stock.

As of April 14, 2021, we had 24,109,635 issued and outstanding shares of common stock, which includes 4,109,635 putative shares of common stock. On April 14, 2021, we once again adjourned our Special Meeting of stockholders in an effort to obtain approval of the Share Increase Ratification effective as of December 4, 2020, which we believe will eliminate any uncertainty with respect to the issuance of such putative shares of common stock. The common stock was held by 120 holders of record. The actual number of holders of our common stock is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street names by brokers or other nominees.

As of April 14, 2021, we had a total of 666,667 shares of our Series C Preferred Stock issued and outstanding. Each share of our Series C Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder would be prohibited from converting Series C Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived upon not less than 61 days' prior written notice to us.

As of April 14, 2021, we had a total of 153 shares of our Series D Preferred Stock outstanding. Each share of our Series D Preferred Stock is convertible into one thousand shares of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder would be prohibited from converting Series D Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived upon not less than 61 days' prior written notice to us.

As of April 14, 2021, we had a total of 875,000 shares of our Series E Preferred Stock issued and outstanding. Each share of our Series E Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder would be prohibited from converting Series E Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived upon not less than 61 days' prior written notice to us.

Recent Sales of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2020 were previously disclosed in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

You should read the following discussion and analysis of financial condition and results of operations in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Item 1A. Risk Factors" and elsewhere in this Form 10 -K. See "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this Form 10 -K.

Overview

We are a medical device company focusing on noninvasive biological response-activating devices that target wound healing and pain therapy and can be administered at home, without the assistance of medical professionals. Our WoundShield, PainShield and UroShield products are backed by novel technology which relates to ultrasound delivery through surface acoustic waves.

Recent Events

COVID-19

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China, and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China and other affected countries. The ongoing COVID-19 pandemic has and may continue to adversely impact our business, as our operations are based in and rely on third parties located in countries affected by the pandemic. Our third-party manufacturer, which is based in China, temporarily shut down for sixty days during 2020 due to the pandemic and became fully operational in April 2020 which led to a significant delay in the production of goods needed to fulfill our sales orders which were scheduled to be fulfilled in our first quarter of 2020. We were able to fulfill these orders in the second quarter of 2020. Additionally, the notified regulatory body we rely on to obtain European CE approval is located in Italy and was shut down for approximately six weeks from March to April 2020, which delayed our submission for CE mark approval for the year 2020. The CE Mark approval was subsequently approved in April 2020. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 have had and may continue to have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The financial downturn has compelled us to furlough or reduce working hours for much of our operating staff, and has forced our remaining staff as well as third-party contractors, to work remotely. In addition, many staff members continue to operate remotely from their homes which is continuing to result in delays in obtaining certain financial records. We also rely on third-party professionals to provide services such as the preparation of our financial statements and to conduct audits, and many of these parties have been affected by government-imposed precautionary measures, thereby delaying our receipt of these services. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases. Therefore, the COVID-19 pandemic has and may again disrupt production and cause delays in the development, supply and delivery of our products, our operation, further divert the attention and efforts of the medical community coping with COVID-19 and disrupt the marketplace in which we operate. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, its variants and the actions to contain COVID-19 or treat its impact, among others. The COVID-19 pandemic could continue to materially disrupt our business and operations, hamper our ability to raise additional funds or sell or securities, continue to slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations.

Business Developments

Effective as of January 2020, the U.S. CMS approved our PainShield™ for reimbursement for Medicare beneficiaries on a national basis. We were notified on March 30, 2020 that our Medicare Enrollment Application was approved, and we are now an approved Medicare Supplier for DME through the National Supplier Clearinghouse, Palmetto-GBA as well as Noridian Administrative Services, LLC, the two Medicare Administrative Contractors that handle DME reimbursement nationwide. PainShield is currently available for Medicare reimbursement on a national level under new HCPCS (Healthcare Common Procedure Coding System) code K1004.

In March 2020, we signed a license agreement with Sanuwave Health, Inc. for the manufacture and delivery of our WoundShield technology. Under the terms of the agreement, we will receive warrants to purchase 127,000 shares of Sanuwave stock, a $250,000 milestone payment based on receipt of U.S. Food and Drug Administration approval, and 10% royalty on Sanuwave's gross revenues from sales or rentals of WoundShield. In return, Sanuwave has received the worldwide, exclusive rights to our WoundShield product and technology. In addition, Sanuwave will bear the costs and clinical validation responsibilities associated with obtaining approval for WoundShield from the U.S. Food and Drug Administration and other regulatory agencies around the world.

In September 2020, the U.S. FDA exercised its Enforcement Discretion to allow distribution of our UroShield device in the United States. This temporary authorization is limited to use as an extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic.

NASDAQ Delisting Procedure

On September 14, 2018, we received a letter from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was no longer in compliance with the minimum stockholders' equity requirement for continued listing on the NASDAQ Capital Market. On October 26, 2018, November 23, 2018 and January 9, 2019, we submitted a plan and supporting documentation to regain compliance with the minimum stockholders' equity requirement and was granted an extension through March 13, 2019 to regain compliance. We were unable to complete a capital raise by March 13, 2019 and were unable to regain compliance by that date.

The Staff notified us by letter dated March 14, 2019 that it determined that we did not meet the terms of the extension because we were unable to complete an equity financing and evidence compliance with the minimum $2.5 million stockholders' equity requirement for continued listing on the NASDAQ Capital Market by March 13, 2019, and our common stock would be subject to delisting from the NASDAQ Capital Market unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel").

We timely requested a hearing before the Panel, which request stayed any delisting action by the Staff. The hearing occurred on May 2, 2019. At the hearing, we presented our plan to evidence compliance with the minimum stockholders' equity requirement for continued listing on the NASDAQ Capital Market, and requested an extension of time within which to do so.

By letter dated May 20, 2019, we received notice that the Panel granted our request for continued listing on the NASDAQ Capital Market. Assuming our compliance plan is executed and compliance with the $2.5 million stockholder equity requirement is demonstrated, the Panel will maintain jurisdiction thereafter for the balance of the 180-day discretionary period and imposed certain conditions and reporting requirements during that period. The Panel determined to continue the listing of our shares of common stock on the NASDAQ Capital Market, partially based upon our assurances that we had a high level of confidence that we would receive the funding needed. The Panel maintained a Panel monitor on the Company until September 2020.

On August 5, 2020, the Company received notice from the Staff indicating that the Company no longer satisfied the Nasdaq Listing Rule 5550(b)(1) (the "Rule"), which requires listed companies to maintain stockholders' equity of at least $2.5 million for continued listing on Nasdaq, and was therefore subject to delisting. In response, the Company timely requested a hearing before the Panel, which request stayed any further action by the Listing Qualifications Staff. The hearing was held on September 24, 2020.

On October 6, 2020, the Company received formal notice that the Panel had granted the Company's request for an extension through December 15, 2020 to evidence compliance with the Rule.

On November 5, 2020, the Company received a subsequent letter from the Nasdaq indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between September 24, 2020, through November 4, 2020, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until May 4, 2021 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with Nasdaq's minimum bid price requirement, the Company's common stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Compliance Period. In the event the Company does not regain compliance by the end of the Compliance Period, the Company may be eligible for additional time to regain compliance. To qualify, the Company will be required to meet the continued listing requirement for the market value of its publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If the Company meets these requirements, the Company may be granted an additional 180 calendar days to regain compliance. However, if it appears to Nasdaq that the Company will be unable to cure the deficiency, or if the Company is not otherwise eligible for the additional cure period, Nasdaq will provide notice that the Company's common stock will be subject to delisting.

On January 4, 2021, the Company received formal notice that the Company has regained compliance with the equity requirement of Nasdaq Listing Rule 5550(b)(1), as required by the Panel decision dated October 6, 2020. Accordingly, the Panel determined to continue the listing of the Company's securities on The Nasdaq Stock Market.

On February 2, 2021, the Company received formal notice that the Staff had determined that for the period from January 19 to February 1, 2021, the closing bid price of the Company's common stock had been at $1.00 per share or greater. Accordingly, the Company regained compliance with Listing Rule 5550(a)(2).

August 2020 Public Offering

On August 27, 2020, we sold an aggregate of 4,531,434 shares of common stock in an underwritten public offering, or the August 2020 Offering, at an offering price to the public of $0.75 per share. We received net proceeds from the August 2020 Offering, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, of approximately $2.7 million.

September 2020 Public Offering

On September 25, 2020, we sold an aggregate of 1,794,783 shares of common stock in an underwritten public offering, or the September 2020 Offering, at an offering price to the public of $1.00 per share. We received net proceeds from the September 2020 Offering, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, of approximately $1.4 million.

December 2020 Private Placement

On December 2, 2020, we entered into a Securities Purchase Agreement with certain institutional and accredited investors pursuant to which the Company issued and sold to such investors in a private placement an aggregate of (i) 5,914,285 shares of the Company's common stock at an offering price of $0.70 per share and (ii) pre-funded warrants to purchase up to 2,657,144 shares of common stock at a purchase price of $0.699 per pre-funded warrant, for gross proceeds of approximately $6.0 million, and net proceeds of approximately $5.4 million.

Option Cancellation

On November 2, 2020, we entered into an option cancellation and release agreement (collectively, the "Cancellation Agreements") with each of Brian Murphy, Christopher Fashek, Martin Goldstein, Michael Ferguson, Stephen Brown, and Thomas Mika (collectively, the "Option holders"), pursuant to which the parties agreed to cancel options to purchase an aggregate of 804,788 shares of our common stock at exercise prices ranging from $2.57 to $6.00 (the "Options") previously granted to each of the Option holders. In exchange for the cancellation of the Options, we paid $1.00 to each Option holder.

Departure of Interim Chief Financial Officer

On October 5, 2020, we and James Cardwell, our former Interim Chief Financial Officer, agreed by mutual understanding that Mr. Cardwell's employment as an officer and employee of the Company will cease as of October 5, 2020, in accordance with the terms of his CFO Consulting Agreement, dated June 1, 2019.

Appointment of Chief Financial Officer

On October 5, 2020, we entered into an Employment Agreement (the "Employment Agreement") with Stephen Brown, pursuant to which we appointed Mr. Brown as Chief Financial Officer, effective October 5, 2020, with a term to continue in effect until terminated by either party. As consideration for his services as Chief Financial Officer, Mr. Brown is entitled to receive (i) an annual base salary of $200,000, less applicable payroll deductions and tax; (ii) reimbursement of any reasonable and customary, documented out-of-pocket expenses actually incurred by Mr. Brown in connection with the performance of his services under the Employment Agreement; and (iii) an annual bonus of $25,000, if earned, as determined by us in our sole discretion. Mr. Brown is also eligible to receive certain grants of incentive stock options to purchase shares of our common stock.

Critical Accounting Policies

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Functional currency

The accompanying consolidated financial statements have been prepared in U.S. dollars.

We believe that the currency of the primary economic environment in which our operations are conducted is the U.S. dollar; thus the dollar is our functional currency. The majority of the proceeds from our financing activities are received in U.S. dollars, and this currency is dominant in management's budgeting and pricing process. Although a portion of our subsidiary's expenses are dominated in NIS (mostly salary, production expenses and facility expenses), a substantial portion of our expenses are denominated in U.S. dollars. In addition, most of our assets and liabilities are in U.S. dollars and while we do invoice and sell products in foreign currencies such as Euros, Great British Pounds and Israeli shekel, we expect that most of our revenues will be generated in U.S. dollars. Furthermore, excess cash flows are repatriated to the U.S. accounts, where they are invested by the parent entity.

Transactions and balances originally denominated in U.S. dollars are presented at their original amounts. Transactions and balances in other currencies have been remeasured into U.S. dollars in accordance with Financial Accounting Standards Board Accounting Standards Codification ("ASC") 830, "Foreign Currency Matters."

All translation gains and losses from the remeasurement of monetary balance sheet items denominated in non-U.S. dollar currencies are reflected in the consolidated statement of operations in financial expenses, net, as appropriate.

Revenue recognition

We generate revenues from the sale of our products to distributors and patients. Revenues from those products are recognized in accordance with ASC 606, *"Revenue Recognition"*, in which its core principle of Accounting Standard Update ("ASU") 2014-09, "Revenue from Contracts with Customers," is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 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 are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

Revenues from sales to distributors are recognized at the time the products are delivered to the distributors ("sell-in"). The Company does not grant rights of return, credits, rebates, price protection, or other privileges on its products to distributors.

Stock-based compensation

We account for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation" ("ASC 718"), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods on a straight-line method in our consolidated statement of operations.

We selected the Black-Scholes-Merton option pricing model as the most appropriate fair value method for our stock-options awards. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term. Expected volatility was calculated based upon similar traded companies' historical share price movements. The expected option term represents the period that our stock options are expected to be outstanding. We currently use the simplified method, in accordance with ASC No.718-10-S99-1 (SAB No. 110), and will continue to do so until sufficient historical exercise data supports using expected life assumptions. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term. The expected dividend yield assumption is based on our historical experience and expectation of no future dividend payouts. We have historically not paid cash dividends and have no foreseeable plans to pay cash dividends in the future.

We apply ASC 505-50, "Equity-Based Payments to Non-Employees" with respect to options and warrants issued to non-employees which requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

Income taxes

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The Company has been consistently in a loss position in the U.S. and at present does not expect that the NOL carryback provision of the CARES Act would result in a material cash benefit to the Company.

We account for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases 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. We provide full valuation allowance, to reduce deferred tax assets to the amount that is more likely than not to be realized.

We implemented a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement.

Warrants

We account for stock warrants held by investors as equity instruments in accordance with ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480"), depending on the specific terms of the warrant agreement.

Debt Issued with Warrants

We consider guidance within ASC 470-20, Debt (ASC 470), ASC 480, and ASC 815, "Derivatives and Hedging" when accounting for the issuance of convertible debt with detachable warrants. As described above under the caption "Warrants", we classify stock warrants as either equity instruments or liabilities depending on the specific terms of the warrant agreement. In circumstances in which debt is issued with liability-classified warrants, the proceeds from the issuance of convertible debt are first allocated to the warrants at their full estimated fair value and established as both a liability and a debt discount. The remaining proceeds, as further reduced by discounts created by the bifurcation of embedded derivatives and a beneficial conversion feature, is allocated to the debt. We account for debt as liabilities measured at amortized cost and amortize the resulting debt discount from the allocation of proceeds, to interest expense using the effective interest method over the expected term of the debt instrument pursuant to ASC 835, "Interest".

Recently issued accounting standards

For a summary of recent accounting pronouncements applicable to our consolidated financial statements see Note 3, "Summary of Significant Accounting Policies" to the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Results of Operations

Twelve Months Ended December 31, 2020 Compared to Twelve Months Ended December 31, 2019

Revenues. For the twelve months ended December 31, 2020 and 2019, our revenues were approximately $623,000 and $530,000, respectively, an increase of approximately 18%, or $93,000, between the periods. The increase was mainly attributable to increased sales from adding distributors. Our revenues may fluctuate as we add new customers or when existing distributors make large purchases of our products during one period and no purchases during another period. Our revenues by quarter may not be linear or consistent. We do not anticipate that our revenues will be impacted by inflation or changing prices in the foreseeable future.

For the twelve months ended December 31, 2020, the percentage of revenues attributable to our products was: PainShield – 92%; WoundShield – 8%; and UroShield – 0%. For the twelve months ended December 31, 2019, the percentage of revenues attributable to our products was: PainShield – 67% and UroShield – 33%. For the twelve months ended December 31, 2020 and 2019, the percentage of revenues attributable to our disposable products was 5% and 4.5%, respectively. For the twelve months ended December 31, 2020 and 2019, the portion of our revenues that was derived from distributors was 93% and 67.5%, respectively.

Gross Profit. For the twelve months ended December 31, 2020 and 2019, gross profit was approximately $214,000 and $281,000, respectively, despite the increase in sales mainly due to larger royalty revenues in 2019 and a large sale to a distributor at little margin.

Gross profit as a percentage of revenues were approximately 34% and 53% for the twelve months ended December 31, 2020 and 2019, respectively. The decrease is primarily due to increased sales in 2020 and a $112,000 sale to a distributor at approximately $18,000 loss. Additionally, in 2019 the Company entered into a licensing agreement pursuant to which the Company received a $150,000 payment which has no associated costs of sales. Our gross profit may be affected year-over-year by the mix of revenues between sales to distributors and sales directly to the end customers (where sales directly to the end customers generally have a higher margin). As a result, we are subject to year-over-year fluctuation in our gross profits.

Research and Development Expenses. For the twelve months ended December 31, 2020 and 2019, research and development expenses were approximately $171,000 and $514,000, respectively, a decrease of approximately 67%, or $343,000 between the periods. This decrease was mainly due to no clinical trials performed during 2020, however there were two employees on payroll dedicated to research and development activities.

Research and development expenses as a percentage of total revenues were approximately 27% and 97% for the twelve months ended December 31, 2020 and 2019, respectively. This decrease was due to the lower costs as described above as well as the increase in revenues.

Our research and development expenses consist mainly of payroll expenses to employees involved in research and development activities, expenses related to subcontracting, patents, clinical trial and facilities expenses associated with and allocated to research and development activities.

Selling and Marketing Expenses. For the twelve months ended December 31, 2020 and 2019, selling and marketing expenses were approximately $993,000 and $1,096,000, respectively, a decrease of approximately 9%, or $103, between the periods. The decrease in selling and marketing expenses was mainly due to COVID-19 restrictions which caused curtailed marketing activities, such as less travel and trade show expenses.

Selling and marketing expenses as a percentage of total revenues were approximately 159% and 207% for the twelve months ended December 31, 2020 and 2019, respectively. The decrease in our percentage was due to the increase in revenues and decrease in selling and marketing expenses.

Selling and marketing expenses consist mainly of payroll expenses to direct sales and marketing employees, stock-based compensation expenses, travel expenses, advertising and marketing expenses, rent and facilities expenses associated with and allocated to selling and marketing activities.

General and Administrative Expenses. For the twelve months ended December 31, 2020 and 2019, general and administrative expenses were approximately $3,769,000 and $3,822,000, respectively, a decrease of approximately 1%, or $53,000, between the periods. Our general and administrative expenses consist mainly of payroll expenses for management and administrative employees, costs associated with being a publicly traded company, stock-based compensation expenses, accounting and facilities expenses associated with general and administrative activities.

Interest expense. For the twelve months ended December 31, 2020 and 2019, were $147,000 and $15,000, respectively, an increase of approximately 879%, or $132,000, between the periods. The increase resulted primarily from 100,000 warrants granted with issuance of notes payable and was recorded as debt discount during 2020.

Change in fair value of derivative liabilities. For the twelve months ended December 31, 2020 and 2019, there was a change in fair value of derivative liabilities resulting in gains of approximately $513,000 and $102,000, respectively. The gain in 2019 was derived from the valuation of derivative liabilities. The derivative liabilities in 2020 were recorded because the Company’s total potentially dilutive shares exceed the Company’s authorized share limit.

Loss on extinguishment of derivative liability. For the twelve months ended December 31, 2020 and 2019, there was a loss on extinguishment of derivative liability of approximately $0 compared to $288,000, respectively. The loss in 2019 was derived from the extinguishment of embedded derivative liabilities upon repayment of its related debt. No other derivative liabilities were extinguished during 2020.

Warrant modification expense. For the twelve months ended December 31, 2020 and 2019, warrant modification expense was approximately $0 and $412,000, respectively. The warrant modification expense in 2019 was related to an amendment to warrants that extended the expiration date by two years. There was no warrant modification in 2020.

Income tax benefit. For the twelve months ended December 31, 2020 and 2019, our income tax (expense) and benefit was approximately ($15,000) and $17,000, respectively. Our income tax benefit for 2019 was a result of favorable adjustments due to lapses of statutes of limitations on its Israel tax positions. In 2020, there was no such adjustment.

Net Loss. Our net loss decreased by approximately $1,469,000, or 25%, to approximately $4,325,000 for the twelve months ended December 31, 2020 from approximately $5,794,000 during the same period in 2019. The decrease in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

We have incurred losses in the amount of approximately $4,325,000 during the year ended December 31, 2020 and had negative cash flow from operating activities of $3,391,00 for the year ended December 31, 2020. Although we expect to continue to incur losses and negative cash flows from operating activities, we had a cash balance of just over $7,533,000 as of December 31, 2020 and therefore, we have sufficient resources to fund our operation for the next twelve months from the date of this filing. The Company may need to continue to raise additional capital to finance its losses and negative cash flows from operations beyond the next twelve months and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability. If we are unable to obtain stockholder ratification of certain prior issuances of our common stock and approval of an increase in the number of authorized shares of our common stock, we will be unable to issue common stock or convertible instruments. As a result, the Company will be limited in its ability to raise additional capital.

During the year ended December 31, 2020, we met our short-term liquidity requirements from our existing cash reserves and proceeds from the sale of our equity securities; $9,479,000 of net proceeds from the sale of common stock in underwritten public offerings, received $200,000 through the issuance of notes payable from a related party and received $42,000 from the Paycheck Protection Program. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments as well as our ability to overcome obstacles that may be presented due to developments caused by the coronavirus outbreak. We expect to continue to incur losses and negative flows from operations. We intend to use the proceeds generated from equity financings, or strategic alliances with third parties, either alone or in combination with equity financing to meet our short-term liquidity requirements as well as to advance our long-term plans. While we believe we have sufficient capital to execute our business plan over the next twelve months, there are no assurances that we will not need to raise additional capital at a later time, or that we would be able to raise additional capital, if required, on terms favorable to us.

We do not have any material commitments to capital expenditures as of December 31, 2020, and we are not aware of any material trends in capital resources that would impact our business.

Twelve Months Ended December 31, 2020 Compared to Twelve Months Ended December 31, 2019

General. As of December 31, 2020, we had cash of approximately $7,533,000, compared to approximately $1,338,000 as of December 31, 2019. We have historically met our cash needs through a combination of issuance of equity, borrowing activities and sales. Our cash requirements are generally for product development, research and development cost, marketing and sales activities, general and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately $3,391,000 for the twelve months ended December 31, 2020 and approximately $3,874,000 for the same period in 2019. The decrease in our net cash used in operating activities in the amount of $483,000 is mainly attributable to the decrease in noncash expense of stock-based compensation, partially offset by deferred revenue and the increase in cash used on accounts payables.

Cash used in our investing activities was approximately $2,000 during the twelve months ended December 31, 2020 compared to cash used in our investing activities was $0 during the twelve months ended December 31, 2019.

Cash provided by financing activities during the twelve months ended December 31, 2020 was approximately $9,522,000 which was mostly the net proceeds received from the sale of common stock in private placements completed in 2020 compared to $4,316,000 in 2019, which was the net proceeds received from the sale of Series E Preferred Stock and common stock in private placements 2019. Our future capital requirements and the adequacy of available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments.

Off Balance Sheet Arrangements

As of December 31, 2020, we have no off-balance sheet transactions, arrangements, obligations, or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment as well issues that may continue to occur due to the development of the coronavirus outbreak. While there were significant delays in the production of goods due to COVID-19 issues, presently, we are no longer experiencing such delays in the production of our products. That said, there are no assurances that if a second wave of the pandemic occurs that we will not experience significant delays in the future. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements and the relevant notes to those statements are attached to this report beginning on page F-1.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

***Disclosure Controls and Procedures*.**

The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act) that are designed to ensure that information required to be disclosed in the Company's Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to the Company's management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Background and Remediation of Material Weakness

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2018, we identified a material weakness in our internal control over financial reporting related to the design and effectiveness of our internal control over financial reporting as described below. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2018, we did not have adequate controls in place to ensure adequate review, including (1) effective controls over our information technology and information systems relevant to the preparation of our financial statements, (2) the controls over managements review procedures for processing, recording and reviewing transactions related to certain contracts, accounting memos and certain monthly closing procedures, and (3) we lacked a formalized written set of policies and procedures including testing documentation to provide evidence that our system of internal controls over financial reporting meets the requirements of the COSO 2013 framework.

During 2019, management developed a remediation plan, whereby we implemented changes to our internal controls for these material weaknesses. Our remediation activities included: (a) expanded consultations with third party specialists on complex accounting matters, financial reporting and regulatory filings, (b) enhanced documentation to support a more precise review process, and (c) enhanced monitoring of the review process.

During the period covered by this annual report on Form 10-K, we have not been able to remediate the material weaknesses identified above. Although the Company has taken numerous steps, our remediation plan is not complete due to the lack of a written testing plan to conclude if our controls and procedures and management were operating effectively; and our remediation plan has not operated for a sufficient period of time for the Company to complete testing to conclude that our newly implemented controls and procedures were operating effectively as of December 31, 2020.

As of December 31, 2020, we did not have adequate controls in place to ensure adequate review, including (1) effective controls over our information technology and information systems relevant to the issuance of securities, (2) the controls over managements review procedures for processing, recording and reviewing such issuances of securities, and (3) we lacked a formalized written set of policies and procedures including testing documentation to provide evidence that our system of internal controls over our issuance of securities meets the requirements of the COSO 2013 framework.

In addition, in connection with the preparation of our consolidated financial statements for the year ended December 31, 2020, we identified another material weakness in our internal control over financial reporting in that we did not properly account for the number of shares of our common stock issued in connection with the conversion of shares of our preferred stock and the exercise of warrants, which resulted in the Company issuing more shares of common stock than are authorized under our governance documents.

While we are seeking stockholder ratification of the increase in the number of authorized shares of common stock and related issuances of such shares, during the period covered by this Annual Report on Form 10-K, we have not been able to remediate the material weakness identified above with respect to the issuance of shares in excess of the number of authorized shares, but we expect to have a plan in place by the end of the second quarter of 2021.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Under the PCAOB standards, a control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit the attention by those responsible for oversight of the company’s financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (Exchange Act). Our management including the Chief Executive Officer and Chief Financial Officer has determined that, as of December 31, 2020, the Company's disclosure controls and procedures are not effective due to a lack of a full and complete testing plan of the Company's disclosure controls and procedures.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, 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. Internal control over financial reporting includes policies and procedures that:

1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the Company; and

3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

With the participation of the Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control — Integrated Framework (2013). Based on this evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, has concluded that our internal control over financial reporting was not effective as of December 31, 2020, as the result of the material weaknesses described above.

As a smaller reporting company, the Company is not required to include in this Annual Report on Form 10-K a report on the effectiveness of internal control over financial reporting by the Company's independent registered public accounting firm.

Management's Remediation Plans

We will look to develop a full testing plan and document to determine that management designs, implements and maintains adequate controls over our financial processes and reporting in the future our controls and procedures and management are operating effectively. To address these internal control deficiencies, management will continue to perform additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

We continue to evaluate the control deficiencies relating to the issuance of shares of our common stock and expect to have a plan of remediation in place by the end of the second quarter of 2021.

Changes in Internal Control over Financial Reporting.

Other than described above in this Item 9A, there have been no changes in our internal control over financial reporting during the year ended December 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On December 4, 2020, certain holders of our Series C Convertible Preferred Stock ("Series C Preferred Stock") converted 396,509 shares of Series C Preferred Stock into shares of our common stock, resulting in an overissue of 246,523 shares of our common stock in excess of the number of authorized shares of our common stock. In December 2020 and January 2021, certain holders of warrants we had issued in December 2020 (the "December 2020 Warrants") exercised a portion of the December 2020 Warrants resulting in an additional overissue of 2,657,144 shares of our common stock. On January 22, 2021, a holder of warrants we previously issued in various offerings (the "Pre-Existing Warrants") exercised a portion of the Pre-Existing Warrants resulting in an additional overissue of 1,205,968 shares of our common stock for a total over-issuance of 4,109,635 shares of our common stock.

Our Board, in consultation with counsel, determined that it is in the best interests of the Company and our stockholders to ratify, pursuant to Section 204 of the Delaware General Corporation Law ("DGCL") and Delaware common law, an increase in the number of authorized shares of our common stock from 20,000,000 to 24,109,635 (the "Authorized Share Increase") and the issuance of 4,109,635 shares of common stock (the "Authorized Share Increase Issuance") upon conversion of the Series C Preferred Stock and the exercise of certain December 2020 Warrants and Pre-Existing Warrants (the "Share Increase Ratification"). On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders (the "Special Meeting") to be held at 10:00 a.m. Eastern time on March 31, 2021 to (i) ratify the Authorized Share Increase and the Authorized Share Increase Issuance, and (ii) further increase the number of our authorized shares of common stock. On March 31, 2021, we did not have the requisite vote to approve the Share Increase Ratification and adjourned the Special Meeting until 10:00 a.m. Eastern time on April 14, 2021 in an effort to obtain additional votes. At the reconvened Special Meeting on April 14, 2021, we again did not have the requisite vote to approve the Share Increase Ratification and further adjourned the Special Meeting until 10:00 a.m. Eastern time on April 27, 2021. Although we have adjourned the Special Meeting in an effort to secure the necessary stockholder approval, there can be no assurance that we will receive the necessary stockholder approval for the Share Increase Ratification. If we do not secure the necessary stockholder approval, we will need to explore other legal options for approval of the Share Increase Ratification.

The failure to approve the Share Increase Ratification may leave us exposed to potential claims that (i) the past issuances of our common stock since December 4, 2020 may not be valid; (ii) the Company does not have sufficient authorized but unissued shares of common stock to permit future sales and issuances of common stock, including pursuant to outstanding shares of preferred stock, warrants and equity awards; and (iii) we would not be able to validate our total outstanding shares of common stock in connection with any strategic transaction that our Board may determine is advisable, including, without limitation, a sale of the Company, a business combination or merger, or a license or other disposition of corporate assets of the Company. Any inability to issue common stock in the future and any invalidity of past issuances of Common Stock could expose us to significant claims and have a material adverse effect on our liquidity, which could result in our filing for bankruptcy or an involuntary petition for bankruptcy being filed against us.

If we do secure stockholder approval of the Share Increase Ratification, we will file a Certificate of Validation with the Secretary of State of the State of Delaware. Even if we file the Certificate of Validation, any claim that (i) the increase in the number of authorized shares of common stock and related issuance of such shares ratified pursuant to the Share Increase Ratification is void or voidable due to a failure of authorization, or (ii) the Delaware Court of Chancery should declare in its discretion that the Share Increase Ratification not be effective or be effective only on certain conditions (collectively, the "Subsequent Claims") may still be brought within 120 days from the time that the filing of the Certificate of Validation with the Secretary of State of the State of Delaware becomes effective in accordance with the Delaware General Corporation Law. We can provide no assurance that Subsequent Claims will not be made within the available time period for making such claims.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required in response to this Item 10 will be set forth in our definitive proxy statement on Schedule 14A for the 2021 annual meeting of stockholders, which shall be filed with the Securities and Exchange Commission no later than April 30, 2021 (the "Proxy Statement").

We have adopted a code of ethics that applies to all of our directors, officers and employees, including the principal executive officer and the principal financial officer. The full text of our code of ethics was filed as Exhibit 14.1 to the annual report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 31, 2017.

ITEM 11. EXECUTIVE COMPENSATION

The information required in response to this Item 11 will be set forth in our Proxy Statement and is incorporated herein by reference.

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

The information required in response to this Item 12 will be set forth in our Proxy Statement and is incorporated herein by reference.

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

The information required in response to this Item 13 will be set forth in our Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required in response to this Item 14 will be set forth in our Proxy Statement and is incorporated herein by reference.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

(1) Financial Statements:

(2) Financial Statement Schedules:

None

(3) Exhibits:

See "Index to Exhibits" for a description of our exhibits.

ITEM 16. FORM 10-K SUMMARY

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
NanoVibronix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of NanoVibronix, Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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
April 15, 2021

NanoVibronix, Inc.
Consolidated Balance Sheets
(Amounts in thousands except share and per share data)

	December 31, 2020	December 31, 2019
ASSETS:		
Current assets:		
Cash	$ 7,142	$ 1,338
Restricted cash	391	-
Trade receivables	25	111
Other accounts receivable and prepaid expenses	267	268
Inventory	145	121
Total current assets	7,970	1,838
Noncurrent assets:		
Fixed assets, net	4	4
Other assets	25	-
Severance pay fund	199	194
Operating lease right-of-use assets, net	31	-
Total non-current assets	259	198
Total assets	$ 8,229	$ 2,036
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Trade payables	$ 144	$ 129
Other accounts payable and accrued expenses	488	280
Shares issued in excess of authorized	2,257	-
Operating lease liabilities, current	13	-
Total current liabilities	2,902	409
Non-current liabilities:		
Accrued severance pay	245	279
Deferred licensing income	199	-
Operating lease liabilities, non-current	18	-
Derivative liabilities	2,471	-
Total liabilities	5,835	688
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Series C Preferred stock of $0.001 par value - Authorized: 3,000,000 shares at December 31, 2020 and December 31, 2019; Issued and outstanding: 666,667 and 2,993,142 at December 31, 2020 and December 31, 2019, respectively	1	2
Series D Preferred stock of $0.001 par value - Authorized: 506 shares at December 31, 2020 and December 31, 2019; Issued and outstanding: 153 and 304 at December 31, 2020 and December 31, 2019, respectively	-	-
Series E Preferred stock of $0.001 par value - Authorized: 1,999,494 shares at December 31, 2020 and December 31, 2019, respectively; Issued and outstanding: 875,000 and 1,825,000 at December 31, 2020 and December 31, 2019, respectively	1	2
Common stock of $0.001 par value - Authorized: 20,000,000 shares at December 31, 2020 and December 31, 2019; Issued and outstanding: 21,246,523 and 4,203,764 shares at December 31, 2020 and December 31, 2019, respectively	22	5
Additional paid in capital	44,959	39,669
Accumulated other comprehensive income	66	-
Accumulated deficit	(42,655)	(38,330)
Total stockholders' equity	2,394	1,348
Total liabilities and stockholders' equity	$ 8,229	$ 2,036

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

NanoVibronix, Inc.
Consolidated Statements of Operations
(Amounts in thousands except share and per share data)

	Year Ended December 31,	
	2020	**2019**
Revenues	$ 623	$ 530
Cost of revenues	409	249
Gross profit	214	281
Operating expenses:		
Research and development	171	514
Selling and marketing	993	1,096
General and administrative	3,769	3,822
Total operating expenses	4,933	5,432
Loss from operations	(4,719)	(5,151)
Interest expense	(147)	(15)
Gain on forgiveness of PPP loan	42	-
Financial income (expense), net	-	(47)
Change in fair value of derivative liabilities	513	102
Loss on extinguishment of derivative liability	-	(288)
Warrant modification expense	-	(412)
Loss before taxes	(4,311)	(5,811)
Income tax (expense) benefits	(15)	17
Net loss	$ (4,325)	$ (5,794)
Basic and diluted net loss available for holders of common stock, Series C Preferred Stock and Series D Preferred Stock	$ (0.42)	$ (0.83)
Weighted average common shares outstanding:		
Basic and diluted	10,298,117	6,939,358
Comprehensive loss:		
Net loss available to common stockholders	(4,325)	(5,794)
Change in foreign currency translation adjustments	66	-
Comprehensive loss available to common stockholders	(4,259)	(5,794)

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

NanoVibronix, Inc.
Consolidated Statement of Stockholders' Equity
(Amounts in thousands except share and per share data)

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid - in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2018	2,733,142	$ 2	304	$ -	-	$ -	3,801,552	$ 4	$ 32,993	$ -	$ (32,536)	$ 463
Issuance of common stock as compensation for services	-	-	-	-	-	-	275,000	-	1,042	-	-	1,042
Stock-based compensation	-	-	-	-	-	-	-	-	713	-	-	713
Sale of common stock	-	-	-	-	-	-	315,000	1	629	-	-	630
Exercise of options	-	-	-	-	-	-	87,212	-	66	-	-	66
Issuance of Series E Preferred Stock	-	-	-	-	1,810,000	2	-	-	3,618	-	-	3,620
Reclassification of warrants	-	-	-	-	-	-	-	-	196	-	-	196
Warrant modification expense	-	-	-	-	-	-	-	-	412	-	-	412
Exchange of Common Stock into Preferred Stock	260,000	-	-	-	15,000	-	(275,000)	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	(5,794)	(5,794)
Balance, December 31, 2019	2,993,142	$ 2	304	$ -	1,825,000	$ 2	4,203,764	$ 5	$ 39,669	$ -	$ (38,330)	$ 1,348
Stock-based compensation	-	-	-	-	-	-	-	-	376	-	-	376
Issuance of common stock for services	-	-	-	-	-	-	375,000	-	566	-	-	566
Issuance of common stock for cash	-	-	-	-	-	-	11,993,979	13	4,225	-	-	4,238
Common stock issued as liability due to lack of authorized shares	-	-	-	-	-	-	1,246,523	1	-	-	-	1
Warrants issued with notes payable	-	-	-	-	-	-	-	-	123	-	-	123
Exchange of Series C Preferred Stock into Common Stock	(2,326,475)	(1)	-	-	-	-	2,326,475	2	-	-	-	1
Exchange of Series D Preferred Stock into Common Stock	-	-	(151)	-	-	-	150,782	-	-	-	-	-
Exchange of Series E Preferred Stock into Common Stock	-	-	-	-	(950,000)	(1)	950,000	1	-	-	-	-
Other comprehensive income	-	-	-	-	-	-	-	-	-	66	-	66
Net loss	-	-	-	-	-	-	-	-	-	-	(4,325)	(4,325)
Balance, December 31, 2020	666,667	$ 1	153	$ -	875,000	$ 1	21,246,523	$ 22	$ 44,959	$ 66	$ (42,655)	$ 2,394

NanoVibronix, Inc.
Consolidated Statements of Cash Flows
(Amounts in thousands except share and per share data)

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (4,325)	$ (5,794)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2	4
Stock-based compensation	376	1,755
Noncash interest expense	123	10
Gain on forgiveness of PPP Loan	(42)	-
Warrants received as licensing fee	(23)	-
Change in fair value of derivative liabilities	(513)	(102)
Other expense related to extension of warrants	-	412
Loss on extinguishment of derivative liability	-	288
Common stock payable to consultant	566	-
Changes in operating assets and liabilities:		
Trade receivable	86	(16)
Other accounts receivable and prepaid expenses	1	(173)
Inventory	(26)	23
Trade payables	15	(64)
Other accounts payable and accrued expenses	209	(167)
Deferred revenue	199	-
Accrued severance pay, net	(39)	(50)
Net cash used in operating activities	(3,391)	(3,874)
Cash flows from investing activities:		
Purchases of property plant and equipment	(2)	-
Net cash used in investing activities	(2)	-
Cash flows from financing activities:		
Proceeds from issuance of notes payable	42	475
Payments of convertible notes	-	(475)
Proceeds from note issued to related party	200	-
Payments of note payable to related party	(200)	-
Proceeds from sale of common stock, net	9,479	630
Proceeds from exercise of warrants	1	-
Proceeds from issuance of Preferred Series E stock	-	3,620
Proceeds from exercise of options	-	66
Net cash provided by financing activities	9,522	4,316
Effects of currency translation on cash	66	-
Net increase in cash, cash equivalents and restricted cash	6,195	442
Cash, cash equivalents and restricted cash at beginning of period	1,338	896
Cash, cash equivalents and restricted cash at end of period	$ 7,533	$ 1,338
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ 5
Cash paid for taxes	$ -	$ -
Supplemental non-cash financing and investing activities:		
Reclass warrants to non-derivative instruments	$ -	$ 196
Discount on notes payable	$ 123	$ 414
Exchange of common stock into Preferred Stock	$ -	$ 275
Reclass from equity to derivative liability due to lack of authorized shares	$ 2,984	$ -
Reclass from equity to liability due to over issuance of shares	$ 2,257	$ -

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

NOTE 1 - DESCRIPTION OF BUSINESS

NanoVibronix, Inc. (the "Company"), a Delaware corporation, commenced operations on October 20, 2003 and is a medical device company focusing on noninvasive biological response-activating devices that target wound healing and pain therapy and can be administered at home, without the assistance of medical professionals.

The Company's principal research and development activities are conducted in Israel through its wholly-owned subsidiary, NanoVibronix Ltd., a company registered in Israel, which commenced operations in October 2003.

NOTE 2 - LIQUIDITY AND PLAN OF OPERATIONS

The Company's ability to continue to operate is dependent mainly on its ability to successfully market and sell its products and the receipt of additional financing until profitability is achieved. The Company currently incurs and historically has incurred losses from operations and expects to do so in the foreseeable future. The Company has historically had recurring losses and negative cash used from operations which raised substantial doubt about the Company's ability to continue as a going concern at that time. In 2020, the Company's net loss of $4,325 and cash used in operations of $3,391 raised substantial doubt of the Company's ability to continue as a going concern. During 2020, the Company also received net proceeds of $9,479 from the sale of our equity securities, received $200 through the issuance of notes payable from a related party and received $42 from the Paycheck Protection Program. Although we expect to continue to incur losses and negative cash flows from operating activities, we had a cash balances of $7,533 and $7,925 as of December 31, 2020 and March 31, 2021, respectively. Because the Company has sufficient resources to fund our operation for the next twelve months from the date of this filing, the substantial doubt has been alleviated. The Company may need to continue to raise additional capital to finance its losses and negative cash flows from operations beyond the next twelve months and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability. If we are unable to obtain stockholder ratification of certain prior issuances of our common stock and approval of an increase in the number of authorized shares of our common stock, we will be unable to issue common stock or convertible instruments. As a result, the Company will be limited in its ability to raise additional capital.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements include the accounts of NanoVibronix, Inc. and its wholly owned subsidiary. Intercompany accounts and transactions have been eliminated. The preparation of these consolidated financial statements and accompanying notes in conformity with U.S. generally accepted accounting principles ("US GAAP") requires management to make estimates and assumptions that affect the amounts reported. Actual results could differ materially from those estimates.

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. The Company believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Foreign currency translation

Non-U.S. dollar denominated transactions and balances have been re-measured to U.S. dollars. All gains and losses from re-measurement of monetary balance sheet items denominated in non-U.S. dollar currencies are reflected in the statements of operations as other comprehensive income, as appropriate. The cumulative translation gains as of the years ended December 31, 2020 and 2019 were $66 and $0, respectively.

Earnings per share

Basic loss per share was computed using the weighted average number of common shares outstanding. Diluted loss per share includes the effect of diluted common stock equivalents. Potentially dilutive securities from the exercise of stock option, warrants and exercise of preferred stock as of December 31, 2020 and 2019, respectively, were excluded from the computation of diluted net loss per share because the effect of their inclusion would have been antidilutive.

Inventory

Inventories are stated at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Cost is determined using the "first-in, first-out" method.

Inventory write-offs are provided to cover risks arising from slow-moving items or technological obsolescence. The Company periodically evaluates the quantities on hand relative to current and historical selling prices and historical and projected sales volume. Based on this evaluation, provisions are made when required to write-down inventory to its net market value. As of December 31, 2020 and 2019, there was no allowance on inventory.

Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, at the following annual rates:

	Years
Computers and peripheral equipment	3
Office furniture and equipment	5-7

Impairment of Long-Lived Assets

Management reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of accounting for the impairment of long-lived assets. If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Consolidated Statements of Operations.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 whereby if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares. This was due to the Company committing more shares than authorized. While temporary suspensions are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the most recent grant date of potentially dilutive instruments. Pursuant to ASC 815, issuances of securities granted as compensation in a share-based payment arrangement are not subject to the sequencing policy.

Derivative Liability

The Company's derivative financial instruments are measured at fair value using the Black Scholes Model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk-free interest rate for the term of the instrument. The liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss under the caption "Change in fair value of derivative liabilities." As of December 31, 2020 and 2019, there were $2,257 and $0 derivative liabilities on the consolidated balance sheet, respectively (see note 7).

Severance pay

The Company's liability for severance pay is for its Israeli employees and is calculated pursuant to Israeli Severance Pay Law based on the most recent salary of the employees multiplied by the number of years of employment as of the balance sheet date, and is in large part covered by regular deposits with recognized pension funds, deposits with severance pay funds and purchases of insurance policies. The value of these deposits and policies is recorded as an asset in the Company's balance sheet. Accrued severance pay liability at December 31, 2020 and 2019 was $245 and $279, respectively.

Revenue recognition

It is the Company's policy that revenues from product sales is recognized in accordance with ASC 606 "Revenue Recognition." Five basic steps must be followed before revenue can be recognized; (1) Identifying the contract(s) with a customer that creates enforceable rights and obligations; (2) Identifying the performance obligations in the contract, such as promising to transfer goods or services to a customer; (3) Determining the transaction price, meaning the amount of consideration in a contract to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer; (4) Allocating the transaction price to the performance obligations in the contract, which requires the company to allocate the transaction price to each performance obligation on the basis of the relative standalone selling prices of each distinct good or services promised in the contract; and (5) Recognizing revenue when (or as) the entity satisfies a performance obligation by transferring a promised good or service to a customer. The amount of revenue recognized is the amount allocated to the satisfied performance obligation. Adoption of ASC 606 has not changed the timing and nature of the Company's revenue recognition and there has been no material effect on the Company's financial statements.

Revenue from product sales is recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from coupons, discounts, chargebacks and distributor fees, processing fees, as well as allowances for returns and government rebates. The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. Collectability of revenue is reasonably assured based on historical evidence of collectability between the Company and its customers.

Revenues from sales to distributors are recognized at the time the products are delivered to the distributors ("sell-in"). The Company does not grant rights of return, credits, rebates, price protection, or other privileges on its products to distributors.

Income taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases 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. The Company provides full valuation allowance, to reduce deferred tax assets to the amount that is more likely than not to be realized.

The Company implements a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement.

The Company recognizes interest and penalties related to uncertain tax positions on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

Stock-based payments

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation", ("ASC 718"), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods on a straight-line method in the Company's consolidated statement of operations.

The Company selected the Black-Scholes-Merton option pricing model as the most appropriate fair value method for its stock-options awards. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term. Expected volatility was calculated based upon similar traded companies' historical share price movements. The expected option term represents the period that the Company's stock options are expected to be outstanding. The Company currently uses the simplified method and will continue to do so until sufficient historical exercise data supports using expected life assumptions. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term. The expected dividend yield assumption is based on the Company's historical experience and expectation of no future dividend payouts. The Company has historically not paid cash dividends and has no foreseeable plans to pay cash dividends in the future.

Recently adopted accounting standards

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. On January 1, 2020, we adopted ASU 2016-02 and its related amendments, which changed our accounting for leases. As a result of this change, we recognized right-of-use assets and lease liabilities on the consolidated balance sheet for all leases with a term longer than 12 months and classified them as operating leases. The right-of-use assets and lease liabilities have been measured by the present value of remaining lease payments over the lease term using our incremental borrowing rates or implicit rates, when readily determinable.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement", which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The adoption of ASU 2018-13 did not have a material effect on consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13") and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, and ASU 2019-05 (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. The Company will be required to adopt this ASU for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The adoption of Topic 326 is not expected to have a material on the Company's financial statements and financial statement disclosures.

NOTE 4 - PREPAID EXPENSES AND OTHER RECEIVABLES

Prepaid expenses and other receivables consist of the following:

	December 31,	
	2020	**2019**
Prepaid expenses	$ 199	$ 249
Other receivables	68	19
	$ 267	$ 268

NOTE 5 – INVENTORY

Inventory consists of the following components:

	December 31,	
	2020	2019
Raw materials	$ 80	$ 88
Finished goods	65	33
	$ 145	$ 121

NOTE 6 - STOCKHOLDERS' EQUITY

Common Stock

The common stock confers upon the holders the right to receive notice to participate and vote in general meetings of the Company, and the right to receive dividends, if declared, and to participate in the distribution of the surplus assets and funds of the Company in the event of liquidation, dissolution or winding up of the Company.

As of December 3, 2020, we had 20,000,000 authorized shares of our common stock and 19,850,014 shares of common stock outstanding resulting in 149,986 shares of common stock being available for issuance. On December 4, 2020, certain holders of the Company's Series C Preferred Stock converted 396,509 shares of Series C Preferred Stock into 396,509 shares of common stock, resulting in an overissue of 246,523 shares of common stock. Beginning on December 17, 2020, through January 22, 2021, certain holders of warrants we had issued in December 2020 (the "December 2020 Warrants") exercised a portion of the December 2020 Warrants for 2,657,144 shares of Common Stock, resulting in an additional overissue of 2,657,144 shares of Common Stock. The aggregate number of shares of common stock that was overissued by the Company was 4,109,635. The shares issued in excess of the authorized amount are classified as liabilities. The common stock equivalents are subject to the Company's sequencing policy and are classified as derivative liabilities (see note 7). On March 3, 2021, the Company filed a proxy statement in connection with a special meeting of stockholders to be held on March 31, 2021 to (i) ratify the increase in the number of authorized shares of common stock from 20,000,000 to 24.109,635 and the issuance of such 4,109,635 shares of common stock, and (ii) further increase the number of our authorized shares of common stock. On March 31, 2021 and April 14, 2021, the Company did not have the requisite vote to approve such proposals and adjourned the Special Meeting until on April 27, 2021 in an effort to obtain additional votes.

Issuance of common stock for cash

During 2019, the Company sold 290,000 shares of common stock to private investors and 25,000 shares to a board member at $2 per share, or $630. The shares also included one warrant for each share of common stock issued.

On August 24, 2020, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC ("Wainwright") (as amended and restated, the "August Underwriting Agreement"). Pursuant to the August Underwriting Agreement, the Company sold, in an upsized firm commitment offering, 4,531,434 shares of the Company's common stock, to Wainwright at an offering price to the public of $0.75 per share, less underwriting discounts and commissions. The Company received net proceeds from the sale of such offering, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company, of approximately $2.7 million. In addition, as partial compensation for Wainwright's services as underwriter in the offering, the Company has issued to Wainwright's designees warrants to purchase 339,858 shares of common stock. The warrants expire on August 24, 2025 and have an exercise price of $0.9375 per share.

On September 22, 2020, the Company entered into an underwriting agreement with Wainwright (as amended and restated, the "September Underwriting Agreement"). Pursuant to the September Underwriting Agreement, the Company sold, in an upsized firm commitment offering, 1,794,783 shares of common stock to Wainwright at an offering price to the public of $1.00 per share, less underwriting discounts and commissions. The Company received net proceeds from the sale of such offering, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company, of approximately $1.4 million. In addition, as partial compensation for Wainwright's services as underwriter in the offering, the Company issued to Wainwright's designees warrants to purchase 134,609 shares of common stock. The warrants expire on September 22, 2025 and have an exercise price of $1.25 per share.

On December 2, 2020, the Company entered into a Securities Purchase Agreement with certain institutional and accredited investors pursuant to which the Company issued and sold to such investors in a private placement (the "*Private Placement*") an aggregate of (i) 5,914,285 shares of the Company's common stock at an offering price of $0.70 per share and (ii) pre-funded warrants to purchase up to 2,657,144 shares of common stock (the "*Pre-funded Warrants*"), at a purchase price of $0.699 per Pre-funded Warrant, for gross proceeds of approximately $6.0 million.

The Pre-funded Warrants have an exercise price of $0.001 per share. The Pre-funded Warrants are immediately exercisable and may be exercised at any time after their original issuance until such Pre-funded Warrants are exercised in full. A holder of a Pre-funded Warrant may not exercise any portion of such holder's Pre-funded Warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding shares of common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise.

The net proceeds to the Company from the Private Placement were approximately $5,400, after deducting placement agent fees and expenses and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Private Placement for general corporate purposes. The Private Placement closed on December 7, 2020.

Issuance of common stock for services

On February 11, 2019, the Company entered into a consulting agreement (the "Agreement") with Bespoke Growth Partners, Inc. ("Bespoke"), pursuant to which, amongst other things, Bespoke was entitled to receive up to 650,000 shares of common stock of the Company, of which 275,000 shares were issued on the date of signing. As of June 30, 2020, 375,000 shares of common stock, valued at $2.25 per share, or $844, was owed to Bespoke. On August 5, 2020, the Company paid $75 and issued an additional 375,000 shares of common stock, valued at $566, or $1.51 per share, to Bespoke under the Agreement. As a result of the change in stock price at issuance, the Company's general and administrative expenses have been reduced by $278.

Series C, D and E Preferred Stock conversion to common stock

Each share of Series E Preferred Stock is convertible at any time and from time to time at the option of a holder of Series E Preferred Stock into one share of the Company's common stock, provided that each holder would be prohibited from converting Series E Preferred Stock into shares of the Company's common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company.

During the twelve months ended December 31, 2020, shareholders converted 950,000 shares of Series E Preferred Stock into 950,000 shares of common stock at a conversion rate of 1 to 1. No purchase was made in order to convert these shares.

Each share of Series D Preferred Stock is convertible into 1,000 shares of common stock at any time at the option of the holders, provided that each holder would be prohibited from converting Series D Preferred Stock into shares of common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 4.99% of the total number of shares of common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company.

During the twelve months ended December 31, 2020, shareholders converted 150.7 shares of Series D Preferred Stock into 150,782 shares of common stock at a conversion rate of 1 to 1,000. No purchase was made in order to convert these shares.

Each share of Series C Preferred Stock is convertible into one share of common stock at any time at the option of the holders, provided that each holder would be prohibited from converting Series C Preferred Stock into shares of common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company.

During the twelve months ended December 31, 2020, shareholders converted 487,890 shares of Series C Preferred Stock into 487,890 shares of common stock at a conversion rate of 1 to 1. No purchase was made in order to convert these shares.

Options and stock based compensation

In February 2019, the Company issued 275,000 shares of common stock to a consultant for services valued at the stock price on the date of issuance which was $3.79 per share, or $1,042. In December 2019, these shares of common stock were converted into Series C Preferred Stock and Series E Preferred Stock, of which 260,000 shares and 15,000 shares were issued, respectively.

During the years ended December 31, 2020 and 2019, 0 and 87,212 employee options were exercised, and 997,000 and 200,000 options were granted, respectively. The options granted during 2020, were recorded at a fair value of $561 and vest at different schedules ranging from date granted to 1 year. The options granted during 2019 were recorded at fair market value of $299 and vested immediately. During the year ended December 31, 2020 and 2019, stock-based compensation expense of $376 and $713 was recorded for options that vested, respectively.

On November 2, 2020, the Company entered into an option cancellation and release agreement with each of Brian Murphy, Christopher Fashek, Martin Goldstein, Michael Ferguson, Stephen Brown, and Thomas Mika (collectively, the "Option holders"), pursuant to which the parties agreed to cancel options to purchase an aggregate of 804,788 shares of common stock of the Company at exercise prices ranging from $2.57 to $6.00 (the "Options") previously granted to each of the Option holders. In exchange for the cancellation of the Options, the Company paid $1.00 to each Option holder.

	Shares Under Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding – December 31, 2018	1,446,587	$ 3.16	7.87
Granted	200,000	3.17	9.41
Forfeited	(3,043)	9.06	(0.89)
Exercised	(48,017)	0.07	(4.24)
Outstanding – December 31, 2019	1,556,332	$ 3.62	6.16
Granted	997,000	0.28	10.12
Forfeited	(804,788)	-	-
Exercised	-	-	-
Outstanding – December 31, 2020	1,748,544	$ 1.59	7.52

The fair value for options granted in 2020 and 2019 is estimated at the date of grant using a Black-Scholes-Merton options pricing model with the following underlying assumptions:

Price at valuation	$ 0.72 – 2.07
Exercise price	$ 0.72 – 2.07
Risk free interest	0.27 – 0.38%
Expected term (in years)	5
Volatility	60.9% - 81.2%

The total stock-based expense recognized in the financial statements for services received from employees and non-employees is shown in the following table.

	Year Ended December 31,	
	2020	2019
Research and development	$ 9	$ -
Selling and marketing	43	44
General and administrative	324	669
Total	$ 376	$ 713

As of December 31, 2020, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $276, which is expected to be recognized over a weighted average period of approximately 0.77 years.

Series C Preferred Stock

Each share of Series C Preferred Stock is convertible into one share of common stock (subject to adjustment) at any time at the option of the holders, provided that each holder would be prohibited from converting Series C Preferred Stock into shares of common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company.

In the event of liquidation, dissolution, or winding up, each holder of Series C Preferred Stock could elect to receive either (i) in preference to any payments made to the holders of Common stock and any other junior securities, a payment for each share of Series C Preferred stock then held equal $ 0.001, plus an additional amount equal to any dividends declared but unpaid on such shares, and any other fees or liquidated damages then due and owing thereon or (ii) the amount of cash, securities or other property to which such holder would be entitled to receive with respect to each share of Series C Preferred Stock if such share of Series C Preferred Stock had been converted to common stock immediately prior to such liquidation, dissolution, or winding up (without giving effect to any conversion limitations).

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the board of directors. However, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the board of directors. The Company is not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Each holder of Series C Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Series C Preferred Stock held by such holder are then convertible (subject to the beneficial ownership limitations) with respect to any and all matters presented to the stockholders for their action or consideration. Holders of Series C Preferred Stock vote together with the holders of common stock as a single class, except as provided by law and except that the consent of holders of a majority of the outstanding Series C Preferred Stock is required to amend the terms of the Series C Preferred Stock.

Series D Preferred Stock

Each share of Series D Preferred Stock is convertible into 1,000 shares of common stock (subject to the beneficial ownership limitations and adjustment as provided in the certificate of designation) at any time at the option of the holders, provided that each holder would be prohibited from converting Series D Preferred Stock into shares of common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 4.99% of the total number of shares of common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until the 61st day after such notice to the Company.

In the event of our liquidation, dissolution, or winding up, each holder of Series D Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series D Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of the Company's capital stock specifically ranking by its terms senior to the Series D Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

Shares of Series D Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the board of directors. However, holders of Series D Preferred Stock are entitled to receive dividends on shares of Series D Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the board of directors, except for stock dividends or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents for which the conversion price will be adjusted. The Company is not obligated to redeem or repurchase any shares of Series D Preferred Stock. Shares of Series D Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

The holders of the Series D Preferred Stock have no voting rights, except as required by law. The Company may not alter or change adversely the powers, preferences and rights of the Series D Preferred Stock or amend the certificate of designation or amend its certificate of incorporation or bylaws in any manner that adversely affects any right of the holders of the Series D Preferred Stock without the affirmative vote of the holders of a majority of the shares of Series D Preferred Stock then outstanding.

The Company is obligated to deliver shares of common stock upon conversion of the Series D Preferred Stock (the "Conversion Shares"), within the time period specified in the certificate of designation. Failure to comply with the timely delivery requirement triggers certain liquidated damages payable by the Company to each of the Series D Preferred Stock holders.

If, at any time while the Series D Preferred Stock is outstanding, the Company completed a Fundamental Transaction (as defined in the certificate of designation), then upon any subsequent conversion of the Series D Preferred Stock, the holder will receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional cash, securities and/or other property or consideration (the "Alternate Consideration") receivable by holders of common stock as a result of such Fundamental Transaction for each share of common stock for which this Series D Preferred Stock is convertible immediately prior to such Fundamental Transaction. For purposes of any such conversion, the determination of the Conversion Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Series D Preferred Stock following such Fundamental Transaction. If such Fundamental Transaction is also a Change of Control Transaction in which the Company is not the surviving entity, then all shares of Series D Preferred Stock shall, upon consummation of such Change of Control Transaction, automatically be converted into Conversion Shares.

Series E Preferred Stock

On June 21, 2019, the Company filed a Certificate of Designation of the Series E Preferred Stock (the "Original Certificate of Designation") with the Secretary of State of the State of Delaware (the "Secretary of State"). The Original Certificate of Designation was effective upon filing with the Secretary of State and designated the Series E Preferred Stock. On July 31, 2019 and November 15, 2019, the Company filed with the Secretary of State an Amended and Restated Certificates of Designation (the "Amended and Restated Certificates of Designation") which were effective upon filing with the Secretary of State of Delaware. The Amended Certificates of Designation provide that, among other things, the Series E Preferred Stock is not convertible into the Company's common stock, and the holders of Series E Preferred Stock had no voting rights, until, in each case, the Company received stockholder approval of the June Offering (as defined below) and the July Preferred Offering (as defined below), which it received on November 18, 2019.

On June 21, 2019, the Company entered into and closed a private placement Securities Purchase Agreement with certain existing stockholders relating to the sale to such existing stockholders of 1,600,000 shares of the Company's Series E Preferred Stock, and seven year warrants to purchase 1,600,000 shares of our Series E Preferred Stock at an exercise price of $2.50 per share, at a purchase price per unit of $2.00 (the "June Offering"), for aggregate proceeds of $3,200 (excluding the exercise of the warrants issued in the June Offering).

On July 31, 2019, the Company entered into and closed a private placement Securities Purchase Agreement with certain existing stockholders relating to the sale to such existing investors of 210,000 shares of the Company's Series E Preferred Stock and seven year warrants to purchase 210,000 shares of our Series E Preferred Stock at an exercise price of $2.50 per share, at a purchase price per unit of $2.00 (the "July Preferred Offering"), for proceeds of $420 (excluding the exercise of the warrants issued in the July Preferred Offering).

Each share of Series E Preferred Stock is convertible at any time and from time to time at the option of a holder of Series E Preferred Stock into one share of the Company's common stock, provided that each holder would be prohibited from converting Series E Preferred Stock into shares of the Company's common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company.

Upon liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, each holder of the Series E Preferred Stock shall be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series E Preferred Stock if such shares had been converted to the Company's common stock immediately prior to such liquidation.

Shares of Series E Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. However, holders of Series E Preferred Stock are entitled to receive dividends on shares of Series E Preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the Board of Directors of the Company. The Company is not obligated to redeem or repurchase any shares of Series E Preferred Stock. Shares of Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Subject to the beneficial ownership limitations, each holder of Series E Preferred Stock shall be entitled to the number of votes equal to the number of shares of the Company's common stock equal to the Voting Ratio. The Voting Ratio, for each share of Series E Preferred Stock is equal to $2.00 divided by $3.53.

These Series E Preferred Shares are classified within permanent equity on the Company's consolidated balance sheet as they do not meet the criteria that would require presentation outside of permanent equity under ASC 480 "Distinguishing Liabilities from Equity".

Warrants

During the year ended December 31, 2019, the Company issued warrants to purchase 190,000 shares of the Company's common stock or Series C Preferred Stock, at an exercise price of the *lesser* of: (a) 80% (*i.e.*, a 20% discount) of the exercise price per share of the warrants to purchase shares of the Company's capital stock issued in the first equity financing of the Company following the date of issuance, or (b) $4.80, with a stipulation that in no event will the exercise price be less than $3.00 per warrant share. The warrants were issued in conjunction with the issuance of convertible debt which has since been repaid and the warrants remain outstanding – See Note 8. The warrants were initially accounted for as a derivative liability until the completion of the June Offering.

The Company issued warrants to purchase 1,600,000 shares of Series E Preferred Stock in the June Offering and warrants to purchase 210,000 shares of Series E Preferred Stock in the July Preferred Offering.

In July and August 2019, the Company issued 315,000 warrants to private investors that were issued in conjunction with the sale of common stock.

During the year ended December 31, 2020, the Company granted 3,774,468 warrants to purchase Company's common in conjunction with the private placements and a seven-year equity warrant to purchase 100,000 shares of the Company's common stock in conjunction with notes payable (see note 7). On December 17, 2020, 1,000,000 pre-funded warrants were exercised at $0.001 per share.

	Warrants
Outstanding – December 31, 2018	2,535,272
Granted	2,315,000
Exercised	-
Expired	-
Outstanding – December 31, 2019	4,850,272
Granted	3,874,468
Exercised	(1,000,000)
Expired	-
Outstanding – December 31, 2020	7,724,740

Warrant modification

On February 5, 2019, the Company entered into amendments to its two-year warrants (the "Warrant Amendment") to purchase an aggregate of 266,667 shares of common stock at an exercise price of $3.00 per share (the "$3.00 Warrants") and warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of $6.00 per share (the "$6.00 Warrants"), issued in January and February 2015, to extend the expiration date of the warrants for two additional years. The warrants were previously extended for two years in January 2017. In addition, the Warrant Amendment amended the exercise price with respect to the $3.00 Warrants from $3.00 per share to $3.35 per share. The exercise price of the $6.00 Warrants was unchanged. Pursuant to the Warrant Amendment, warrants to purchase 266,667 shares of common stock at $3.35 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share will expire on January 29, 2021, and warrants to purchase 140,000 shares of common stock at $6.00 per share will expire on February 10, 2021, and warrants to purchase 13,333 shares of common stock at $6.00 per share will expire on February 23, 2021. The Warrant Amendment is effective as of January 29, 2019. All other terms of the original warrants remain the same.

The Warrant Amendment was accounted for in warrant modification expense, which was measured at the amount equal to the incremental value reflecting the change in the fair value of the warrants before and after the Warrant Amendment. Accordingly, warrant modification expense in the amount of $412 was recorded with a corresponding increase in the additional paid-in capital.

In estimating the warrants' fair value, the Company used the following assumptions:

Risk free interest	2.56%
Dividend yield	0%
Volatility	55.6% - 56.5%
Contractual term (in years)	2

NOTE 7 - NOTES PAYABLE AND DERIVATIVE LIABILITIES

Convertible Notes

On March 29, 2019, the Company completed a bridge financing, pursuant to which the Company issued to two accredited investors convertible notes on the aggregate principal amount of $225 (the "Notes") and seven-year warrants (the "March Warrants") to purchase an aggregate of 90,000 shares of the Company's common stock or Series C Preferred Stock. These warrants were initially accounted for as a derivative liability.

Between April and May 2019, the Company completed multiple bridge financings, pursuant to which the Company issued to two accredited investors convertible notes in the aggregate principal amount of $250 and seven-year warrants to purchase an aggregate of 100,000 shares of the Company's common stock or Series C Preferred Stock with the same terms as the notes issued on March 29, 2019.

In June 2019, the Company paid off all convertible notes and interest with funds raised from an equity financing of $2,000, or Qualified Financing. The balance of the notes and interest paid off was $475 and $5, respectively. As a result, a loss of $288 was recorded on extinguishment of derivative liabilities upon payoff of convertible notes.

PPP Loan

In May 2020, the Company was granted a loan (the "PPP Loan") in the amount of $42, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the Coronavirus Aid, Relief, and Economic Securities ("CARES") Act, which was enacted March 27, 2020. The application for these funds required the Company to, in good faith, certify that the current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to consider its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The Company made this good faith assertion based upon the adverse impact the COVID-19 pandemic had on its business and the global economy. While the Company has made this assertion in good faith based upon all available guidance, management will continue to assess their continued qualification if and when updated guidance is released by the Treasury Department. The receipt of these funds, and the forgiveness of the loan attendant to these funds, is dependent on the Company having initially qualified for the loan and qualifying for the forgiveness of such loan based on its future adherence to the forgiveness criteria.

The PPP Loan, which was in the form of a note that was granted on May 14, 2020, matures in two years and accrues interest at a rate of 1.00% per annum, payable in monthly payments commencing six months after loan disbursement. The Company also has the option to negotiate with the lender to extend the maturity date to up to five years. The note may be prepaid by the Company at any time prior to maturity with no prepayment penalties. Funds from the PPP Loan may only be used for payroll costs and any payments of certain covered interest, lease and utility payments. The Company has used the entire PPP Loan amount for qualifying expenses in the covered period. Under the terms of the PPP, certain amounts of the PPP Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. 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, the amount forgiven is applied to outstanding principal. The Company was granted full forgiveness for the loan in the 4th quarter of 2020 and recorded a gain on forgiveness of $42.

Unsecured Note

On June 22, 2020, the Company issued and sold to a related party an unsecured promissory note in the principal amount of $200, which accrues interest at 10% per annum and matures in one year. On August 28, 2020, the Company paid the note in full including $4 of accrued interest.

Notes payable:		
Principal value of 6% convertible notes issued during the six months ended June 30, 2020	$	475
Fair value of derivative liability of convertible notes prior to payoff date		122
Debt discount less amortization during the period prior to payoff date		(410)
Loss on extinguishment of derivative liabilities upon payoff of convertible notes		288
Payoff of convertible notes		(475)
Total carrying value of notes payable at December 31, 2019	$	-
Principal value of unsecured note issued during year ended December 31, 2020	$	242
Forgiveness of notes payable		42
Payoff of unsecured note		(200)
Total carrying value of notes payable at December 31, 2020	$	-

In addition to the promissory note, the Company granted a seven-year equity warrant to purchase 100,000 shares of the Company's common stock. The exercise price for each warrant share is equal to $2.50, and the warrants may also be exercised, in whole or in part, by means of a cashless exercise. The warrants were recognized as a debt discount and is amortized over the life of the note. The warrants were valued at $123 using a Black Scholes Merton pricing model with the following underlying assumptions:

Price at valuation	$	2.21
Exercise price	$	2.50
Risk free interest		0.34%
Expected term (in years)		7
Volatility		60.7%

Derivative Liabilities

On March 29, 2019 the Company issued 90,000 warrants in conjunction with the issuance of convertible debt.

Between April and May 2019, the Company issued 100,000 warrants in conjunction with the issuance of convertible debt. These warrants were initially accounted for as a derivative liability.

As of June 26, 2019, the Company completed a Qualified Financing, at which point the warrants exercise price is fixed and therefore the warrants no longer require derivative treatment. The warrants were remeasured at fair value on that date and the remaining derivative liability of $196 reclassed to equity.

During 2020, the Company established a sequencing policy to which common stock equivalents are exercisable to shares of common stock more than the Company's authorized limit. It was determined that all options and warrants by the end of the year were no longer permitted to be classified as equity and were valued at fair market value using Black Scholes and recorded as derivative liabilities.

A summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's purchase warrants that were categorized within Level 3 of the fair value hierarchy during the year ended December 31, 2020 is as follows:

Stock price	$	0.72 - $1.09
Conversion price	$	0.07 - $6.00
Contractual term (in years)		0.16 - 5
Volatility (annual)		77.1% - 211%
Risk-free rate		0.09% - 0.27%

The foregoing assumptions were reviewed quarterly and were subject to change based primarily on management's assessment of the probability of the events described occurring.

Financial Liabilities Measured at Fair Value on a Recurring Basis

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices included in Level 1, that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

There were no transfers between Level 3 during the years ended December 31, 2020 and 2019.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2020 and 2019:

	Derivative Liability - -Warrants	Embedded Conversion Feature Derivative Liability	Value of Common Stock Equivalents in Excess of Shares Authorized	Total Derivative Liabilities
Balance - January 1, 2019	$ -	$ -	$ -	$ -
Liabilities	$ 261	$ 159	-	$ 420
Change in fair value of warrant liability	(65)	(37)	-	(102)
Eliminate derivative treatment	(196)	(122)	-	(318)
Balance – December 31, 2019	$ -	$ -	$	$ -
Liabilities	-	-	2,983	2,983
Change in fair value of derivative liability	-	-	(513)	(513)
Eliminate derivative treatment	-	-		
Balance – December 31, 2020	$ -	$	$ 2,471	$ 2,471

Note 8 – LEASES

The Company has operating lease agreements with terms up to 3 years, including car leases.

The Company adopted ASC 842 effective January 1, 2020 using the cumulative-effect adjustment transition method, which applies the provisions of the standard at the effective date without adjusting the comparative periods presented. The Company adopted the following practical expedients and elected the following accounting policies related to this standard update:

- The option to not reassess prior conclusions related to the identification, classification and accounting for initial direct costs for leases that commenced prior to January 1, 2020.

- Short-term lease accounting policy election allowing lessees to not recognize right-of-use assets and liabilities for leases with a term of 12 months or less; and

- The option to not separate lease and non-lease components for certain equipment lease asset categories such as freight car, vehicles and work equipment.

- The package of practical expedients applied to all of its leases, including (i) not reassessing whether any expired or existing contracts are or contain leases, (ii) not reassessing the lease classification for any expired or existing leases, and (iii) not reassessing initial direct costs for any existing leases. The assets and liabilities from operating and finance leases are recognized at the commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. Short-term leases, which have an initial term of 12 months or less, are not recorded on the balance sheet.

The Company's operating leases do not provide an implicit rate that can readily be determined. Therefore, the Company uses a discount rate based on its incremental borrowing rate, which is determined using the average of borrowing rates explicitly stated in the Company's convertible debt.

The Company's weighted-average remaining lease term relating to its operating leases is 2.52 years, with a weighted-average discount rate of 10%.

The Company incurred $16 of lease expense for its operating leases for the year ended December 31, 2020.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of December 31, 2020:

2021	15
2022	10
2023	10
Total undiscounted operating lease payments	35
Less: Imputed interest	4
Present value of operating lease liabilities	$ 31

NOTE 9 - LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDER

Basic net loss per common share ("Basic EPS") is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. All outstanding share options and warrants for the years ended December 31, 2020 and 2019 have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented.

The following table summarizes the Company's securities, in common share equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	December 31, 2020	December 31, 2019
Series D Preferred Stock Shares	153,000	303,782
Series E Preferred Stock Shares	875,000	1,825,000
Stock Options - employee and non-employee	1,748,544	1,556,332
Warrants	7,724,740	266,667
Total	10,501,284	3,951,781

The diluted loss per share equals basic loss per share in the year ended December 31, 2020 and 2019 because the Company had a net loss and the impact of the assumed exercise of stock options and the vesting of restricted stock would have been anti-dilutive.

NOTE 10 - GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

Summary information about geographic areas:

The Company manages its business on the basis of one reportable segment and derives revenues from selling its products directly to patients as well as through distributor agreements. The following is a summary of revenues within geographic areas:

	Year Ended December 31,	
	2020	**2019**
United States	$ 467	$ 331
Europe	147	168
Israel	3	14
India	1	12
Other	5	5
Total	$ 623	$ 530

The Company's long-lived assets are all located in Israel.

NOTE 11– OTHER ASSETS

On April 9, 2020, pursuant to a licensing agreement entered into in March 2020, the Company received 10-year warrants to purchase 127,000 shares of Sanuwave Health, Inc. at a price of $0.19 per share. The fair value for warrants received is estimated at the date of grant using a Black-Scholes-Merton pricing model with the following underlying assumptions:

Price at valuation	$ 0.19 – 0.26
Exercise price	$ 0.19
Risk free interest	0.66 - 0.73%
Expected term (in years)	10
Volatility	140.6 – 143.9%

The Company considers this to be level 3 inputs and is valued at each reporting period. The fair value of these warrants for the year ended December 31, 2020 was $24. There was a net $0 change in fair value during the year ended December 31, 2020.

NOTE 12 - COMMITMENTS AND CONTINGENCIES

Pending litigation

On December 17, 2019, a lawsuit was filed by a former officer and director, Jona Zumeris, in the Haifa Israel District Financial Court, seeking damages of approximately $900 for breach of the Separation Agreement executed on July 4, 2018. The Israeli court issued a court order demanding that we restrict approximately $700 of the Company's money until the matter is adjudicated. The Company appealed the court order and in February 2020, the Company agreed to restrict approximately 1,187 NIS ("New Israeli Shekel") and agreed to try to settle the matter in mediation. On November 30, 2020, the Company funded the escrow account with $391. In January 2021, the parties reached a settlement in which the Company paid the plaintiff approximately $366 as settlement in full.

Other Risks

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic, and the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common shares.

NOTE 13 – RELATED PARTY TRANSACTIONS

Sale of common stock and Series E Preferred Stock

In June and July 2019, the Company sold and aggregate of 1,810,000 shares of Series E Preferred Stock to existing shareholders for $2.00 per share, or $3,620.

In November 2019, the Company sold 25,000 shares of common stock to a board member at $2 per share, or $50.

NOTE 14 – INCOME TAXES

As of December 31, 2020, the U.S. Company had federal and state net operating loss carry forward for tax purposes of approximately $ 25,369. $11,410 of the federal net operating loss can be carried forward indefinitely and $13,959 of the federal net operating loss can be offset against taxable income for 20 years. State net operating losses can also be carried forward for 20 years. Utilization of the U.S. net operating losses may be subject to substantial limitations in the event of a change of ownership under the provisions of the Internal Revenue Code of 1986.

Income tax expense is comprised of the following:

	Year ended December 31,	
	2020	2019
Current Tax		
Federal		
State	$ -	$ -
Foreign	14,621	(17,072)
Total	$ 14,621	$ (17,072)
Deferred Tax		
Federal	$ (584,419)	$ (1,151,693)
State	(5,043)	(358,828)
Foreign	$ 2,140	-
Total	$ (587,323)	$ (1,510,521)
Less: Valuation Allowance	587,323	1,510,521
Total Tax	$ 14,621	$ (17,072)

The difference between the statutory tax rate of the Company and the effective tax rate is primarily the result of tax benefits generated by the Company and its subsidiary which have not been recognized due to the uncertainty that such tax benefits will ultimately be realized. A reconciliation of the statutory U.S Federal rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2020	2019
Federal income tax benefit at statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	0.12%	6.17%
Foreign rate differential	-0.08%	-0.03%
Permanent Items	2.22%	-1.78%
Change in valuation allowance	-13.63%	-25.99%
Return to provision adjustments	-4.03%	0%
Forfeited options	-7.33%	0%
Other	-1.39%	0.92%
Effective tax rate	-0.34%	0.29%

Foreign tax

Tax rates applicable to the income of the Israeli subsidiary:

The Israeli corporate tax rate in 2020 and 2019 is 23%.

The subsidiary has final tax assessments through 2015.

Loss / (income) before taxes on income:

	Year ended December 31,	
	2020	2019
Domestic	$ 4,380	$ 5,853
Foreign	(70)	(42)
	$ 4,310	$ 5,811

Deferred income taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	Year ended December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carry forward	$ 5,712	$ 4,807
Stock compensation and other	175	484
Deferred tax assets before valuation allowance	5,887	5,291
Valuation allowance	(5,887)	(5,291)
Net deferred tax asset	$ -	$ -

For the year ended December 31, 2020 and 2019, the net increases in valuation allowance of $596 and $1,510, respectively was primarily driven by the increase in net operating loss carryforwards.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that all or some portion of the deferred tax assets will not be realized.

The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences are deductible and net operating losses are able to be utilized. Based on consideration of these factors, the Company concluded that all of its recorded deferred tax assets are not more likely than not realizable and recorded a full valuation allowance at December 31, 2020 and 2019.

The Company considers the earnings of its non-U.S. subsidiary to be indefinitely invested outside the United States on the basis of estimates that future domestic cash generation will be sufficient to meet future domestic cash needs and our specific plans for reinvestment of those subsidiary earnings. We have not recorded a deferred tax liability related to the U.S. federal and state income taxes as an estimate of undistributed earnings of foreign subsidiaries would not be practicable to estimate at this time. If the Company does decide to repatriate the foreign earnings, we would need to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely invested outside the United States.

Reconciliation of the theoretical tax expense to the actual tax expense

The main reconciling items between the statutory tax rate of the Company and the effective tax rate are the non-recognition of tax benefits from accumulated net operating loss carryforward among the Company and its subsidiary due to the uncertainty of the realization of such tax benefits.

The Company recognizes interest and penalties related to unrecognized tax benefits in tax expense. During the year ended December 31, 2020, the Company accrued $0 for interest and penalties expenses related to uncertain tax positions.

U.S. federal and New York State income taxes are open for examination for years 2018-2020 and Israel tax returns are open for examination for years 2017-2020.

NOTE 15 - SUBSEQUENT EVENTS

Warrant Exercises

On January 21, 2021, Company entered into letter agreements (the “Letter Agreements”) with certain existing accredited investors to exercise certain outstanding warrants (the “Existing Warrants”) to purchase up to an aggregate of 1,205,968 shares of the Company’s common stock at an exercise price per share of $1.165 (the “Exercise”). Certain of the Existing Warrants (the “Registered Existing Warrants”) and the shares of common stock underlying the Registered Existing Warrants have been registered pursuant to a registration statement on Form S-3 (File No. 333-251264) and a registration statement on Form S-1 (File No. 333-218871). In consideration for the exercise of the Existing Warrants for cash, the exercising holders will receive new unregistered warrants to purchase up to an aggregate of 1,205,967 shares of common stock (the “New Warrants”) at an exercise price of $1.04 per share and with an exercise period of seven years from the initial closing date. The gross proceeds to the Company from the Exercise were approximately $1.4 million.

Over-issuance

On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders (the “Special Meeting”) to be held at 10:00 a.m. Eastern time on March 31, 2021 to (i) ratify the increase in the number of authorized shares of common stock from 20,000,000 to 24.109,635 and the issuance of such 4,109,635 shares of common stock, and (ii) further increase the number of our authorized shares of common stock. On March 31, 2021 and April 14, 2021, the Company did not have the requisite vote to approve such proposals and adjourned the Special Meeting until on April 27, 2021 in an effort to obtain additional votes.

Index to Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (as presently in effect) (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 17, 2015)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
3.3	Certificate of Amendment of Certificate of Incorporation (creating the Series C Preferred Stock) (incorporated by reference to Exhibit 3.3 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 7, 2017)
3.5	Certificate of Designation, Preferences, Rights and Limitations of Series E Preferred Stock (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 19, 2019)
3.6	Certificate of Amendment of the Amended and Restated Certificate of Designation (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 21, 2019)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
4.2	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.4 to Amendment No. 4 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 31, 2017)
4.3	Form of Unit Purchase Option (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 18, 2017)
4.4	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 18, 2017)
4.5	Form of May 10 and May 15, 2019 Warrants (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019)
4.6	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2019)
4.7	Form of Preferred Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019)

4.8	Form of Common Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019)
4.9	Form of Warrant Amendment (incorporated by reference to Exhibit 4.10 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on May 20, 2020)
4.10	Form of Underwriter Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 26, 2020).
4.11	Form of Underwriter Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2020).
4.12	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
4.13	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
4.14*	Description of Securities
10.1	Fourteenth Amended and Restated Securities Purchase Agreement, dated June 16, 2014, by and between NanoVibronix, Inc. and Globis Overseas Fund, Ltd. (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.2	Fourteenth Amended and Restated Securities Purchase Agreement, dated December 11, 2014, by and between NanoVibronix, Inc. and Globis Capital Partners, L.P. (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.3	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2014, by NanoVibronix, Inc. in favor of and Globis Overseas Fund, Ltd. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.4	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2014, by NanoVibronix, Inc. in favor of and Globis Capital Partners, L.P. (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.5	Form of Amended and Restated 2013 and 2014 Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.13 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2014)
10.6+	NanoVibronix, Inc. 2004 Global Share Option Plan (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.7+	Personal Employment Agreement, dated March 1, 2008, by and between Nano-Vibronix (Israel 2003) Ltd and Jona Zumeris (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)

10.8+	Form of Indemnification Agreement between NanoVibronix, Inc. and certain of its officers and directors (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.9	Amendment to Subscription Agreement Convertible Promissory Notes, dated February 28, 2014, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.10	Second Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2014, by and between NanoVibronix, Inc. and the holders signatory thereto (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.11	Third Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2014, by and between NanoVibronix, Inc. and the holders signatory thereto (incorporated by reference to Exhibit 10.20 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.12+	NanoVibronix, Inc. 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.27 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
10.13+	First Amendment to Personal Employment Agreement, dated June 16, 2014, by and between NanoVibronix, Inc. and Dr. Jona Zumeris (incorporated by reference to Exhibit 10.29 to Amendment No. 8 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 23, 2014)
10.14	Services Agreement, dated March 25, 2015, by and between Multigon Industries, Inc. and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.35 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.15+	Employment Agreement, dated March 25, 2015, by and between William Stern and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.36 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.16+	Warrant to Purchase Common Stock, dated March 25, 2015 (incorporated by reference to Exhibit 10.38 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.17+	Letter Agreement, dated March 25, 2015, by and between NanoVibronix, Inc. and Martin Goldstein (incorporated by reference to Exhibit 10.39 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.18+	Form of Incentive Stock Option Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.40 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.19+	Form of Nonqualified Stock Option Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.41 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.20+	Form of Restricted Stock Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.42 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)

10.21+	Form of 3(i) Award Agreement under the Israeli Appendix to the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.22+	Form of 102 Award Agreement under the Israeli Appendix to the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.44 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.23+	Employment Agreement, dated October 13, 2016, by and between NanoVibronix, Inc. and Brian Murphy (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016)
10.24	Form of Amendment to Warrant to Purchase Common Stock, effective as of January 27, 2017 (incorporated by reference to Exhibit 10.46 to the Annual Report on Form 10-K filed with the Securities Exchange Commission on March 31, 2017)
10.25	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2017)
10.26	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2017)
10.27	Convertible Promissory Note, dated March 23, 2017, by and between NanoVibronix, Inc. and an individual investor (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2017)
10.28	Warrant to Purchase Common Stock, dated March 23, 2017, by and between NanoVibronix, Inc. and an individual investor (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2017)
10.29+	First Amendment to Nonqualified Stock Option Agreement, dated March 30, 2017, between NanoVibronix, Inc. and Ira A. Greenstein (incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K filed with the Securities Exchange Commission on March 31, 2017)
10.30+	First Amendment to Nonqualified Stock Option Agreement, dated March 30, 2017, between NanoVibronix, Inc. and Ira A. Greenstein (incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K filed with the Securities Exchange Commission on March 31, 2017)
10.31+	Offer Letter, dated October 14, 2016, between NanoVibronix, Inc. and Christopher M. Fashek (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016)
10.32+	Nonqualified Stock Option Agreement, dated October 14, 2016, between NanoVibronix, Inc. and Christopher M. Fashek (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016)
10.33	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017)
10.34	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017)
10.35	Form of Letter Agreement, dated September 7, 2017, between NanoVibronix, Inc. and holders of the 2017 Notes (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K/A filed with the Securities and Exchange Commission on September 14, 2017)

10.36	Consulting Agreement dated as of February 21, 2019, between NanoVibronix, Inc and Bespoke Growth Partners, Inc. (incorporated by reference to Exhibit 10.36 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019)
10.37	Convertible Promissory Note (incorporated by reference to Exhibit 10.37 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019)
10.38	Convertible Promissory Note (incorporated by reference to Exhibit 10.38 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019)
10.39	Form of Warrant (incorporated by reference to Exhibit 10.39 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019)
10.40	Convertible Promissory Note (Globis), May 10, 2019 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019)
10.41	Convertible Promissory Note (AiGH), May 15, 2019 (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019)
10.42+	CFO Consulting Agreement, dated as of June 1, 2019, between NanoVibronix Inc. and James S. Cardwell (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 4, 2019)
10.43	Securities Purchase Agreement, dated as of June 21, 2019, by and among the Company and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2019)
10.44	Securities Purchase Agreement, dated as of July 31, 2019, by and among the Company and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019)
10.45	Securities Purchase Agreement, dated as of July 31, 2019, by and among the Company and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019)
10.46	Form of Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2020).
10.47	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2020).
10.48	Note with Cross River Bank (SBA-Payroll Protection Program loan) dated May 14, 2020 (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 19, 2020).
10.49+	Employment Agreement, dated as of October 5, 2020, between NanoVibronix, Inc. and Stephen Brown (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 8, 2020).

10.50+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Brian Murphy (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.51+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Christopher Fashek (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.52+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Martin Goldstein (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.53+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Michael Ferguson (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.54+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Stephen Brown (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.55+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Thomas Mika (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.56	Form of Securities Purchase Agreement, dated December 2, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
10.57	Form of Registration Rights Agreement, dated December 2, 2020 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
10.58*#	Amended and Restated Distribution Agreement for “Private Label” Products dated December 10, 2020 by and between NanoVibronix, Inc. and Ultra Pain Products Inc.
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
23.1*	Consent of Marcum, LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Stockholders’ Deficiency, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.

* Filed herewith.

** Furnished herewith.

\+ Management contract or compensatory plan or arrangement.

\# Certain portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K. The omitted information is (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NANOVIBRONIX, INC.

By: */s/ Brian Murphy*
Brian Murphy
Chief Executive Officer

Date: April 15, 2021

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian Murphy as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto 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 he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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.

Signature	Title	Date
/s/ BRIAN MURPHY Brian Murphy	Chief Executive Officer and Director (principal executive officer)	April 15, 2021
/s/ STEPHEN BROWN Stephen Brown	Chief Financial Officer, (principal financial and accounting officer)	April 15, 2021
/s/ CHRISTOPHER FASHEK Christopher Fashek	Chairman of the Board of Directors	April 15, 2021
/s/ MARTIN GOLDSTEIN Martin Goldstein	Director	April 15, 2021
/s/ HAROLD JACOB M.D. Harold Jacob, M.D.	Director	April 15, 2021
/s/ MICHAEL FERGUSON Michael Ferguson	Director	April 15, 2021
/s/ THOMAS R. MIKA Thomas R. Mika	Director	April 15, 2021

Exhibit 4.14

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of May 14, 2020, NanoVibronix, Inc., a Delaware corporation ("we," "our" and the "Company") has its common stock, par value $0.001 per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The following description is intended as a summary and is qualified in its entirety by reference to our amended and restated certificate of incorporation, as amended (the "Amended & Restated Certificate of Incorporation") and the amended and restated by-laws, as amended (the "By-laws") as currently in effect, copies of which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein.

Authorized Capital Stock

As of April 14, 2021, our authorized capital stock consists of 31,000,000 shares, of which 20,000,00 shares are common stock, par value $0.001 per share, and 11,000,000 shares are preferred stock, par value $0.001 per share, 3,000,000 of which have been designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), 506 of which have been designated as Series D Convertible Preferred Stock ("Series D Preferred Stock") and 1,999,494 of which have been designated as Series E Convertible Preferred Stock ("Series E Preferred Stock"). As of April 14, 2021, there were 24,109,625 shares of common stock issued and outstanding, which includes 4,109,635 putative shares of common stock, 666,667 shares of Series C Convertible Preferred Stock issued and outstanding, 304 shares of Series D Convertible Preferred Stock issued and outstanding and 875,000 shares of Series E Convertible Preferred Stock issued and outstanding.

Our Board, in consultation with counsel, determined that it is in the best interests of the Company and our stockholders to ratify, pursuant to Section 204 of the Delaware General Corporation Law ("DGCL") and Delaware common law, an increase in the number of authorized shares of our common stock from 20,000,000 to 24,109,635 (the "Authorized Share Increase") and the issuance of 4,109,635 shares of common stock (the "Authorized Share Increase Issuance") upon conversion of the Series C Preferred Stock and the exercise of certain December 2020 Warrants and Pre-Existing Warrants (the "Share Increase Ratification"). On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders (the "Special Meeting") to be held at 10:00 a.m. Eastern time on March 31, 2021 to (i) ratify the Authorized Share Increase and the Authorized Share Increase Issuance, and (ii) further increase the number of our authorized shares of common stock. On March 31, 2021, we did not have the requisite vote to approve the Share Increase Ratification and adjourned the Special Meeting until 10:00 a.m. Eastern time on April 14, 2021 in an effort to obtain additional votes. At the reconvened Special Meeting on April 14, 2021, we again did not have the requisite vote to approve the Share Increase Ratification and further adjourned the Special Meeting until 10:00 a.m. Eastern time on April 27, 2021. Although we have adjourned the Special Meeting in an effort to secure the necessary stockholder approval, there can be no assurance that we will receive the necessary stockholder approval for the Share Increase Ratification.

Common Stock

Voting Rights

Each stockholder has one vote for each share of common stock held on all matters submitted to a vote of stockholders. A stockholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those stockholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our Amended & Restated Certificate of Incorporation and By-laws provide that stockholder actions may be effected at a duly called meeting of stockholders or pursuant to written consent of the majority of stockholders.

Dividend Rights

The holders of outstanding shares of common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that the board of directors (the "Board") may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. However, the current policy of our Board is to retain earnings, if any, for operations and growth.

No Preemptive or Similar Rights

The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of the Board and issued in the future.

Right to Receive Liquidation Distributions

Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution.

The NASDAQ Capital Market Listing

Our common stock is listed on the NASDAQ Capital Market ("NASDAQ") under the symbol "NAOV."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

Options and Warrants

As of April 14, 2021, we had 1,748,544 shares of common stock issuable upon exercise of outstanding options and 7,724,740 shares of common stock issuable upon the exercise of warrants. There are no other outstanding warrants or options at this time.

Preferred Stock

We may issue any class of preferred stock in any series. The Board has the authority, subject to limitations prescribed under Delaware law and the rights of the holders of any series of preferred stock, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. The number of authorized shares of preferred stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of our capital stock entitled to vote thereon, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any preferred stock designation. The Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of common stock and the voting and other rights of the holders of common stock.

Series C Convertible Preferred Stock

Conversion Rights

Each share of the Series C Preferred Stock is convertible into one (1) share of common stock, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of common stock if, as a result of such conversion, the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. However, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the Board. The Company is not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Voting Rights

Except as provided in the Designation, Preferences, Rights and Limitations of Series C Preferred Stock or as otherwise required by law, each holder of Series C Preferred Stock will be entitled to the number of votes equal to the number of shares of common stock into which such share of Series C Preferred Stock could be converted, provided that the holder would be prohibited from converting Series C Preferred Stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding, for purposes of determining the shares entitled to vote at any regular, annual or special meeting of stockholders of the Company, and shall have voting rights and powers equal to the voting rights and powers of the common stock (except as otherwise expressly provided herein or as required by law, voting together with the common stock as a single class) and shall be entitled to notice of any stockholders' meeting in accordance with the By-laws of the Company. Fractional votes shall not, however, be permitted and any fractional voting rights shall be rounded to the nearest whole number (with one-half being rounded upward). We may not, without the written consent of holders of a majority of the then issued and outstanding shares of Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, pari passu with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described above.

Series D Convertible Preferred Stock

Conversion Rights

Each share of the Series D Preferred Stock is convertible into one thousand (1,000) shares of common stock, provided that the holder will be prohibited from converting Series D Preferred Stock into shares of common stock if, as a result of such conversion, the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series D Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series D Preferred Stock. The conversion rate of the Series D Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. Series D Preferred Stockholders ("Series D Holders") are entitled to receive, and the Company shall pay, dividends on shares of Series D Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends shall be paid on shares of Series D Preferred Stock.

Voting Rights

Except as provided in the Series D Preferred Stock Certificate of Designation or as otherwise required by law, Series D Holders shall have no voting rights. However, as long as any shares of Series D Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the Series D Holders of a majority of the then outstanding shares of the Series D Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series D Preferred Stock or alter or amend the Series D Preferred Stock Certificate of Designation, (b) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the Series D Holders, (c) increase the number of authorized shares of Series D Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Series D Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the Series D Preferred Stock were fully converted (disregarding for such purpose any conversion limitations hereunder) to common stock which amounts shall be paid pari passu with all holders of common stock. The Company shall mail written notice of any such liquidation, not less than 30 days prior to the payment date stated therein, to each Series D Holder.

Series E Convertible Preferred Stock

Conversion Rights

Each share of Series E Preferred Stock is convertible at any time and from time to time at the option of a holder of Series E Preferred Stock (a "Series E Holder") into one share of our common stock, provided that each holder is prohibited from converting Series E Preferred Stock into shares of our common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company. The conversion rate of the Series E Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series E Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. However, Series E Holders are entitled to receive dividends on shares of Series E Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the Board. The Company is not obligated to redeem or repurchase any shares of Series E Preferred Stock. Shares of Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Voting Rights

Each Series E Holder shall be entitled to the number of votes equal to the number of shares of our common stock equal to the voting ratio, which, for each share of Series E Preferred Stock, is equal to $2.00 divided by $3.53. Fractional votes shall not, however, be permitted and any fractional voting rights resulting from the above formula (after aggregating all shares into which shares of Series E Preferred Stock held by each Series E Holder could be converted) shall be rounded to the nearest whole number (with one-half being rounded upward).

Liquidation Rights

Upon liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, each Series E Holder shall be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series E Preferred Stock if such shares had been converted to our common stock immediately prior to such liquidation.

Delaware Anti-Takeover Law and Provisions of our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law (the "DGCL"). Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, or controlling, or controlled by, the entity or person. The term "owner" is broadly defined to include any person that, individually, with or through that person's affiliates or associates, among other things, beneficially owns the stock, or has the right to acquire the stock, whether or not the right is immediately exercisable, under any agreement or understanding or upon the exercise of warrants or options or otherwise or has the right to vote the stock under any agreement or understanding, or has an agreement or understanding with the beneficial owner of the stock for the purpose of acquiring, holding, voting or disposing of the stock.

The restrictions in Section 203 do not apply to corporations that have elected, in the manner provided in Section 203, not to be subject to Section 203 of the DGCL or, with certain exceptions, which do not have a class of voting stock that is listed on a national securities exchange or authorized for quotation on the Nasdaq Stock Market or held of record by more than 2,000 stockholders. Our certificate of incorporation and bylaws do not opt out of Section 203.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and By-laws

The provisions of our Amended and Restated Certificate of Incorporation and By-laws may delay or discourage transactions involving an actual or potential change in our 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. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Certificate of Incorporation and By-laws:

- permit our board of directors to issue up to 11,000,000 shares of preferred stock, without further action by the stockholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;

- provide that the authorized number of directors may be changed only by resolution of a majority of the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships (the "Whole Board");

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

- provide that special meetings of our stockholders may be called only by a resolution adopted by a majority of the Whole Board; and

- set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our Board, of candidates for election as directors and with regard to business to be brought before a meeting of stockholders.

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

[***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

AMENDED AND RESTATED DISTRIBUTION AGREEMENT FOR "PRIVATE LABELED" PRODUCTS

This Amended and Restated Distribution Agreement (this ***"Agreement"***) is made and entered into on this 10th day of December, 2020 (***"Effective Date"***), by and between: **NanoVibronix, Inc.**, having its principal place of business at 525 Executive Boulevard, Elmsford, NY 10523 (hereinafter, the ***"Supplier"***); and **Ultra Pain Products Inc.**, having its principal place of business at 745 Shotgun Road, Suite D, Sunrise, FL 33326 (hereinafter, the ***"Purchaser"***) (the aforesaid herein referred to individually as a ***"Party"*** and together as the ***"Parties"***).

RECITALS

WHEREAS, Supplier own certain intellectual property rights in connection with its proprietary PainShield® technology, and is engaged in the manufacture of certain PainShield® products incorporating said technology and relating to acoustic treatment of tissues for a variety of medical applications

WHEREAS, on June 19, 2020, the Parties entered into and executed that certain Distribution Agreement (hereinafter, the ***"Original Agreement"***), effective as of said execution date, pursuant to which Supplier granted Purchaser certain exclusive rights to sell and distribute the Products in the Field within the Territory;

WHEREAS, *Section 2.2* of that Original Agreement grants Purchaser certain rights to negotiate a separate contract with Supplier for "private labeled" Products;

WHEREAS, pursuant to that *Section 2.2* of that Original Agreement, and subject to the terms and conditions set forth herein, Supplier and Purchaser desire to hereby enter into such a contract for the manufacture and supply of "private labeled" Products;

WHEREAS, subject to the terms and conditions of this Agreement, Supplier agrees to sell, and Purchaser agrees to purchase, the Private Labeled Products, and Purchaser shall have the exclusive right to purchase such Private Labeled Products from Supplier;

WHEREIN, in the interest of consistency in language and uniformity of the Parties' conduct, the Parties desire that the Original Agreement be amended and restated in its entirety as set forth herein; and

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the receipt and sufficiency of which is hereby acknowledged, the Original Agreement is hereby amended and restated in its entirety as follows:

1. DEFINITIONS

1.1. ***"Products"*** means Supplier's proprietary PainShield® devices and any related accessories, components thereof, and attachments thereto, which utilize acoustic ultrasound for medical treatments, including pain relief and the inhibition of infections not relating to wound care, as more specifically identified in the attached Appendix A. Should Supplier release, during the Term of this Agreement, any new or updated versions of the subject PainShield® devices, related accessories, components thereof, or attachments thereto, including (but not limited to) Supplier's recently released PainShield®Plus™, such new or updated versions shall be included within the scope of Products as defined herein. For the avoidance of doubt, the Products shall not encompass Supplier's certain other products relating to its other proprietary technologies, such as and specifically including Supplier's WoundShield® and UroShield® devices and related technologies.

1.2. ***"Private Labeled Products"*** means products that are substantially the same as Supplier's Products that have been manufactured and "private labeled" for Purchaser in accordance with Purchaser's approved Specifications, for resale by Purchaser under Purchaser's label(s), brand(s), or trademark(s).

1.3. ***"Specifications"*** as used herein refers to one or more of the overall aesthetic design, visual appearance and color, form, functional performance, compatibility and operational characteristics, raw materials, labeling, packaging, and instructions relating to manufacture or use of the Private Labeled Products, as well as compliance with applicable standards relating to the Private Labeled Products.

1.4. ***"Territory"*** means the United States of America.

1.5. ***"DME Distributor"*** as used herein means a domestic (U.S.) individual or entity licensed by a local, state, or regional organization to supply medical products classified as ***"Durable Medical Equipment ("DME"), Prosthetics, Orthotics and Supplies"*** (***"DMEPOS"***) to customers or end users within the Territory.

1.6. ***"Protected Customers"*** means customers or end users to whom Purchaser or Purchaser's DME Distributors sell the Private Labeled Products during the Term, as established from sales records provided to Supplier pursuant to Purchaser's and Purchaser's DME Suppliers' reporting obligations under **Section 3.10.**

1.7. ***"Field"*** as used in connection with the exclusive right granted to Purchaser hereunder means (a) Purchaser's sales of the Private Labeled Products within the Territory to or through DME Distributors; and (b) Purchaser's continued sales of the Private Labeled Products and Products to its Protected Customers. Specifically excluded from the Field are: (a) direct sales of Products that have not been privately labeled, *except* for direct sales of Products to Purchaser's Protected Customers; (b) any sales of Products or Private Labeled Products to any Veteran's Facilities; and (c) any sales of Products or Private Labeled Products made pursuant to a Federal Supply Schedule.

1.8. ***"Registration"*** means all registrations, permissions, consents, approvals, or licenses (including, without limitation, those required to be made with or given by (as appropriate) any governmental department or any enforcement body constituted under the law of the Territory for licensing or other regulatory purposes relating to the Products) required to enable the Products to be lawfully marketed, distributed, and sold in the Territory.

1.9. ***"Confidential Information"*** means information of a Party that is identified or reasonably understood as being confidential or constitutes proprietary or trade secret information, that is disclosed to the other Party or otherwise becomes known by the other Party during the Term or that was disclosed to the other Party or otherwise became known by the other Party between the effective date of the Original Agreement and the Effective Date hereof. Such Confidential Information may include, without limitation: business plans, customer lists, financial statements, flow charts, product plans, technical information, and/or relevant intellectual property know-how. Moreover, all contents, terms, and conditions of this Agreement, as well as any documents or verbally-shared information relating to this Agreement, constitute Confidential Information.

1.10. ***"Control"*** as used in **Section 7.2** herein, means the direct or indirect possession of power to direct or cause the direction of management or policies of a Party, whether through ownership, stock, or other securities, by contract, or otherwise. Ownership of more than fifty percent (50%) of the beneficial interest of a Party shall be conclusive evidence that Control of such Party exists.

2. GRANT OF RIGHTS

2.1. Pursuant to this Agreement, and in consideration of Purchaser paying Supplier, on even date herewith, an up-font sum of **$30,000 (USD**) (as the separate "licensing fee" referenced in Section 2.2 of Original Agreement), Supplier hereby grants to Purchaser, for the Term of this Agreement, the exclusive right to domestic (U.S.) sales of the Private Labeled Products within the Field as defined in **Section 1.7**.

2.2. In addition Purchaser's aforementioned exclusive right to sell Private Labeled Products within the Field, Supplier further grants Purchaser the exclusive right to sell Products and the Private Labeled Products to its Protected Customers for a period of twelve (12) months following the date of Purchaser's or a DME Supplier's first sale to the Protected Customers, which shall be based on records submitted to Supplier in accordance with Purchaser's and DME Distributors' reporting obligations under **Section 3.10**. The Private Labeled Products manufactured for and supplied to Purchaser by Supplier pursuant to this Agreement shall conform to Purchaser's approved Specifications. Supplier agrees that it shall not itself produce or manufacture, or authorize, request, or permit any third-party to produce or manufacture the Private Labeled Products.

2.3. Supplier retains the exclusive right to modify: (a) the Products, and, by extension, the Private Labeled Products based upon such Products, including by deleting and/or adding certain Products, related accessories, components thereof, or attachments thereto; and (b) subject to **Section 5.1** (guaranteeing prices through the end of 2021), the prices for any Private Labeled Products as currently listed in Appendix A.

2.3.1. **Modification of Products.** Supplier's right to modify Private Labeled Products under this Section is subject to such modification (i) being reasonable, (ii) not materially altering the Specifications for the Private Labeled Products, and (iii) Supplier providing Purchaser with written notice of the modification at least sixty (60) days prior to such modification becoming effective. Any modifications to Private Labeled Products departing from the original Specifications shall require the mutual written agreement of the Parties.

2.3.2. **Modification of Price.** Supplier's right to modify the pricing of the Private Labeled Products under this Section is subject to such modification (i) being reasonable, (ii) not increasing the current prices by more than [***]%, and (iii) Supplier providing Purchaser with written notice of the price modification at least sixty (60) days prior to such modification becoming effective.

2.4. The rights granted under this **Section 2** are contingent on and subject to Purchaser (a) paying the up-front sum of **$30,000 (USD)** pursuant to **Section 2.**1, and (b) having met its obligations under the Original Agreement through the end of the current fiscal year (2020), specifically the minimum order requirements and payments of all associated invoices pursuant to the terms of the Original Agreement. For clarification, the foregoing are prerequisites to this Agreement becoming effective.

3. GENERAL RIGHTS AND OBLIGATIONS

3.1. **Private Labeled Products.** Purchaser hereby agrees to purchase Private Labeled Products exclusively and solely from Supplier, and Supplier hereby agrees to manufacture Private Labeled Products in accordance with Purchaser's Specifications and to supply Purchaser with Private Labeled Products in quantities set forth in Accepted Purchase Orders.

3.2. **Minimum Order Requirement.** In order to meet the quarterly and yearly minimum order requirements of this Agreement, Purchaser hereby agrees that it shall purchase the Private Labeled Products in at least the quantities specified in Tables 1-4 of Appendix C.

3.3. **Specifications for Private Labeled Products.** In consideration Purchaser's up-front payment of **$30,000** concurrently made on the Effective Date of this Agreement, Supplier agrees to provide Purchaser with certain proposed Specifications for the Private Labeled Products no later than February 1, 2020. Subject to Purchaser's final approval, the final Specifications for the Private Labeled Products shall be mutually agreed upon by the Parties. Specifications approved by Purchaser for the Private Labeled Products must be able to be manufactured in a manner that is reasonably similar to the Supplier's current manufacturing process.

3.4. **Promotion of Private Labeled Products.** It is the sole responsibility of Purchaser to, in a commercially reasonable manner: (i) market and promote the Private Labeled Products at relevant tradeshows, conferences, and other networking events; (ii) line up and interact with DME Distributors; (iii) educate DME Distributors and/or end users about the Private Labeled Products; and (iv) service reasonable requests from end users (including patients and physicians) relating to the Private Labeled Products. For purposes of promoting the Private Labeled Products, Purchaser and DME Distributors to whom Purchaser sells the Private Labeled Products shall have the right and a royalty-free license to use Supplier's relevant trademarks for purposes of promoting, marketing or selling Private Labeled Products in the Territory.

3.5. **Purchaser Pricing of Labeled Products.** Purchaser and any DME Distributors to whom Purchaser sells Private Labeled Products shall have the right to set resale prices, bill, and collect payments for its sales of Private Labeled Products, subject to the following:

3.5.1. Information or documents relating to Purchaser's and any DME Distributors' pricing of the Private Labeled Product shall not be publicized, including (but not limited to) on any websites, in public forums, events, or discussions, on any social media platform, or in printed publications. Furthermore, Purchaser's and any DME Distributor's pricing of the Private Labeled Products shall not be disclosed to any third-party that has not specifically requested a price quote for the Private Labeled Products.

3.5.2. Any non-public pricing set by Purchaser and any DME Distributor in connection with its resale of the Private Labeled Products to end users or consumers shall not be below the manufacturer's list price. That is, the manufacturer's list price is the *minimum* price at which Purchaser and any DME Distributor may sell the Private Labeled Products, and excludes any applicable sales tax, VAT, and freight charges.

3.5.3. The manufacturer's list price for the Products (not privately labeled) as of the Effective Date of this Agreement is $[***]. Any change in the manufacturer's list price for the Products shall be communicated to Purchaser in writing.

3.6. **Limitations.** Purchaser hereby acknowledges that the exclusive right granted under this Agreement is for the purchase of Private Labeled Products from Supplier, and the subsequent domestic sale of said Private Labeled Products to or through DME Distributors.

3.7. **Modifications and Branding.** Purchaser acknowledges that in no event shall Purchaser or any DME Distributor alter, disassemble, reassemble, or modify in any way any Private Labeled Products purchased from Supplier. Purchaser further acknowledges that it shall not alter any of the Supplier's trademarks appearing on the Private Labeled Products, packaging, or inserts.

3.8. **Warranties.** Purchaser acknowledges that it shall sell the Private Labeled Products under Supplier's Limited Warranty, included in Appendix B hereto. Purchaser agrees that it shall not make any representations or give any warranties concerning the Private Labeled Products or the capabilities of the Private Labeled Products which are false or misleading in any way or go beyond the warranties and representations made by Supplier in this Agreement.

3.9. **FDA Requirements.** To ensure continued compliance with the U.S. Food and Drug Administration's ("**FDA**") requirements, Purchaser and any DME Distributors to whom Purchaser sells Private Labeled Products shall not, directly or indirectly, supply any Private Labeled Products comprising a PainShield® device to patients without first obtaining an order or prescription from a physician, if applicable FDA rules or regulations so require. Purchaser and any DME Distributors to whom Purchaser sells Private Labeled Products shall be responsible for maintaining records of all such physician prescriptions for orders of Private Labeled Products that include a PainShield® device.

3.10. **Reporting.** To ensure compliance with FDA requirements as set forth in **Section 3.9** above and also in the event of any Private Labeled Product becoming subject to a recall, Purchaser and any DME Distributors to whom Purchaser sells Private Labeled Products shall maintain, during the Term, a complete record of all sales and distributions of Private Labeled Products, including all invoices, including at least the following information: customer name, date of sale, shipment date, serial number(s) of Private Labeled Products, and any physician prescriptions for any orders of Private Labeled Products that include a PainShield® device pursuant to **Section 3.9** above. The complete records maintained by Purchaser and DME Distributors shall be promptly supplied to Supplier on at least a bi-annual basis, subject to any applicable rules, regulations, or statutes regarding patient or consumer privacy and other applicable laws and regulations. Failure to comply with the reporting obligations under this Section shall void Supplier's general warranty (provided in Appendix B) for any Private Labeled Products not reflected in Purchaser's or DME Distributors' records.

3.11. **Confidentiality.** Each Party hereto agrees that, except as otherwise required by law, it shall keep confidential and not publicly disclose during the Term, and for a period of three (3) years thereafter, any Confidential Information as defined in **Section 1.10** hereof, including the contents of this Agreement. Notwithstanding the foregoing, each Party's confidentiality obligations with respect to Confidential Information that constitutes a trade secret under the laws of any jurisdiction within the Territory shall survive until such Confidential Information is no longer deemed to be a trade secret under such applicable law.

3.12. **DME Distributors.** Purchaser shall be responsible for all DME Distributors to whom it sells Products or Private Labeled Products adhering to the terms set forth in **Sections 3.5-3.11** above. The failure of Purchaser or any DME Distributor to whom it sells Products or Private Labeled Products to comply with the requirements of this section and as specifically set forth in **Sections 3.5-3.11** above, and Purchaser's or DME Distributor's failure to remedy such noncompliance within ten (10) days after receiving written notice thereof, shall constitute a breach and result in Supplier having the unilateral right to terminate this Agreement. As acknowledgment of Supplier's liability assumed hereunder, Supplier has executed a written acknowledgment of its obligations and the obligations assumed with respect to any DME Distributors to whom it sells Private Labeled Products in Appendix D hereto.

3.13. **No Assignment.** Neither Party shall assign or delegate to a third-party any of its rights, interests, or obligations under this Agreement without prior written consent from the other Party. No assignment, delegation, or subcontract by either Party shall relieve such Party from its obligations and liabilities under this Agreement.

3.14. **Non-Compete.** Purchaser hereby acknowledges that, during the Term and continuing for a period of six (6) months after expiration or termination of this Agreement, Purchaser shall not market, distribute, or sell in the Territory any medical or pain management devices that compete with Supplier's Products.

4. PURCHASE ORDERS

4.1. **Purchase Orders.** Purchaser's orders for Private Labeled Products shall be submitted to Supplier in a form mutually agreed upon by the Parties and consistent with the terms of this Agreement (***"Purchase Order"***). At a minimum, a Purchase Order for Purchaser's requested Private Labeled Products must: (a) identify the specific Private Labeled Products being ordered (e.g., by model or product number(s)) and designated quantities thereof; and (b) allow for a lead time of at least thirty (30) business days commencing on the date of Supplier's receipt of the Purchase Order.

4.2. **Acceptance of Purchase Orders.** Upon written confirmation from Supplier specifying (a) the lead time needed for manufacture of Private Labeled Products listed in a Purchase Order, and (b) the Total Cost thereof, the subject Purchase Order shall be deemed "accepted" (***"Accepted Purchase Order"***). An Accepted Purchase Order cannot be canceled and the Total Cost specified in an Accepted Purchase Order is not refundable.

5. PRICING AND PAYMENT TERMS

5.1. **Pricing.** The prices at which Supplier will sell Private Labeled Products to Purchaser are set forth in Appendix A hereto. All prices or cost schedules included with this Agreement for Private Labeled Products constitute an introductory start-up price that is guaranteed by Supplier through the end of the 2021 calendar year. Thereafter, pursuant and subject to **Section 2.2** of this Agreement and the limitations thereof, one or more of the Private Labeled Products and/or the prices of such Private Labeled Products are subject to modification by Supplier. For clarification, the prices of Private Labeled Products in this Section refer to the prices at which Supplier agrees to manufacture and sell Private Labeled Products to Supplier and Supplier agrees to purchase the Private Labeled Products from Supplier in quantities meeting the minimum order obligations of **Section 2.2** and set forth in Appendix C.

5.2. **Taxes.** Any prices listed herein for Private Labeled Products do not include applicable sales, use, value-added, excise or any other tax, duty, or charge that may now be or later become imposed by applicable federal, state, or other authority. Any such applicable taxes, duties, or other charges are the sole responsibility and shall be included in the Total Cost to be fully paid by Purchaser pursuant to, or in addition to (if charges incurred later) Supplier's invoiced amounts for each Accepted Purchase Order.

5.3. **Invoicing.** Supplier's invoice for Private Labeled Products sold to Purchaser will be remitted to Purchaser on the date Supplier accepts a Purchase Order in the form of or as part of the Accepted Purchase Order. The invoiced amount of an Accepted Purchase Order (***"Total Cost"***) includes: (a) the cost of Private Labeled Products based on the type(s) and quantity(ies) of Private Labeled Product(s) specified in Purchaser's Purchase Order based on the applicable pricing schedule; (b) any applicable sales, use, value added, excise or any other tax, duty, or charge that is in effect or will be imposed by any federal, state or other authority (see **Section 5.2** above); (c) all applicable shipping and freight costs; and (d) 10% of any shipping insurance costs.

5.4. **Payments.** Pursuant to **Section 5.2** above, Purchaser shall be provided the Total Cost of each Purchase Order in the form of an Accepted Purchase Order. Upon issuance of an Accepted Purchase Order, the Total Cost provided therein shall be due and payable as specified below.

5.4.1. **Initial 50% of Total Cost Before Manufacture.** At least half (50%) of the Total Cost set forth in an Accepted Purchase Order shall be paid by Purchaser within 2 business days following the issuance date of the Accepted Purchase Order. As this initial payment by Purchaser is a prerequisite to Supplier beginning manufacture of the Private Labeled Products specified in the Accepted Purchase Order, delayed payment by Purchaser is reasonably likely to delay and extend the estimated lead times for Supplier's completion of the Purchase Order.

5.4.2. **Remaining 50% of Total Cost Before Final Delivery.** The remaining 50% of the Total Cost shall be paid by Purchaser upon receipt of Supplier's written notification confirming that the Private Labeled Products specified in the Accepted Purchase Order have been manufactured and are ready for Final Delivery. As Purchaser's payment in full of the Total Cost is a prerequisite for the Final Delivery of the Private Labeled Products to Purchaser, delayed payment by Purchaser will delay Final Delivery of the Private Labeled Products to Purchaser by at least the same extent.

5.4.3. **Late Payments.** Purchaser's timely payments of invoices for accompanying Accepted Purchase Orders are essential for achieving the objectives of this Agreements. Any invoiced amount not timely paid in full within thirty (30) days shall incur an interest charge of 10%. For purposes of this Section, timeliness of Purchaser's payment shall be calculated from: (a) the issuance date of the Accepted Purchase Order with respect to the payment due under **Section 5.4.1**, and (b) Supplier's written notification of manufactured Private Labeled Products being ready for Final Shipment with respect to the payment due under **Section 5.4.2**.

6. COMMERCIAL TERMS

6.1. **Shipping**: Supplier shall serve as the fulfillment center for Purchaser's orders of Private Labeled Products. All "final shipments" of Private Labeled Products to Purchaser will be from Tyler, Texas via United States Postal Service Priority Mail, UPS, and/or Fed Ex (as specified) (***"Final Shipment"***). Although costs of shipping Products to Purchaser are not reflected in Supplier's pricing of the Private Labeled Products, Purchaser shall be solely responsible for all costs of the "final shipments" of Private Labeled Products, and also for 10% of any shipping insurance charges, as reflected in the Total Cost.

6.2. **Delivery.** Private Labeled Products purchased from Supplier by Purchaser shall be delivered consistent with the terms of this Agreement and in accordance with Purchaser's standard terms for Purchase Orders. Title and risk of loss for Private Labeled Products shall be deemed to pass to Purchaser upon Supplier's tender of the Private Labeled Products for Final Shipment to the delivery location designated by Purchaser in the applicable Purchase Order (or to such other location as mutually agreed by the Parties) ("**Delivery Location**"). ***"Final Delivery"*** means that the relevant Private Labeled Products have been delivered to the Delivery Location and accepted by Purchaser (or the applicable DME Distributor if the Delivery Location is a location owned or controlled by a DME Distributor).

6.3. **Warranty & Returns.** Pursuant to Supplier's "General Warranty and Return Policy" included in Appendix B hereto, Private Labeled Products sold to Purchaser pursuant to this Agreement are warranted by Supplier for twelve (12) months following the date of Final Delivery and shall (a) conform to the applicable Specifications, (b) be fit for their intended purpose and operate as intended, (c) be merchantable, (d) and not infringe or misappropriate any third party's patent or other intellectual property rights. Supplier's warranty of the Private Labeled Products shall pass through and apply to end-users that purchase the Private Labeled Products from Purchaser or from a DME Distributor to whom Purchaser sold the Private Labeled Products. Supplier's warranty does not apply to shields (patches). Although included in the Private Labeled Products of this Agreement, the shields are warranted only to be merchantable, suitable for their intended use, and shall not infringe or misappropriate any third party's patent or other intellectual property rights, and such warranty ceases to apply following first use/application of said shield. Also specifically excluded by Supplier's warranty are Private Labeled Products that have been subject to: (i) misuse or accident; (ii) attempted repair by a person that has not been specifically authorized by Supplier to perform said repair; or (iii) use in a manner that is not specifically authorized or approved in the User Manual for such Private Labeled Products.

6.4 **Inspection and Rejection of Nonconforming Products**. Purchaser (or the applicable DME Distributor if a shipment is sent directly to a DME Distributor) has the right to inspect the Private Labeled Products on or after the date of delivery. Purchaser (or the applicable DME Distributor), at its sole option, may inspect all or a sample of the Private Labeled Products in such shipment, and may reject all or any portion of such Private Labeled Products if it determines such Private Labeled Products are nonconforming (including by failure to adhere to the Specifications), damaged, or defective. If Purchaser (or a DME Distributor) rejects any portion of the Private Labeled Products, Purchaser (or the applicable DME Distributor) has the right, effective upon written notice to Supplier, to require replacement of such rejected Private Labeled Products from Supplier pursuant to Supplier's General Warranty and Return Policy.

7. TERM AND TERMINATION

7.1. **Term.** Subject to the termination of this Agreement by a Party as set forth herein, the Term of this Agreement shall begin on the Effective Date and continue until the end of the 2023 calendar year (***"Initial Term"***). At the end of the Initial Term, and annually thereafter, the Agreement will automatically renew for an additional one (1) year term (***"Renewal Term,"*** and, together with the Initial Term, the "**Term**"), or for one or more additional Renewal Term(s) as the case may be, *provided that:* (a) Purchaser has met the minimum purchase requirements as set forth herein; and (b) neither Party has provided written notice to the other Party of its desire to not renew the Agreement. Should a Party desire to *not renew* the Agreement for a Renewal Term, written notice of the same must be provided to the other Party at least thirty (30) days prior to the end of the Initial Term or any subsequent Renewal Term then in effect.

7.2. **Termination by Parties.** Either Party may terminate this Agreement upon providing the other Party with written notice of its desire to terminate no less than ninety (90) days before the date of termination. A Party's exercise of its rights to terminate under this Section shall not affect or eliminate its or the other Party's obligations under this Agreement during the prerequisite notice period, i.e., before the date of the termination.

7.3. **Failure to Meet Minimum Order Requirements.** Should Purchaser fail to meet (a) the minimum quarterly order requirements for any two (2) successive calendar quarters, or (b) the minimum yearly order requirement for any one (1) calendar year, Supplier shall have the right to unilaterally terminate this Agreement.

7.4. **Effect of Termination.** Termination of this Agreement by either Party shall not affect Purchaser's accrued obligations to pay for Private Labeled Products ordered by Purchaser pursuant to an Accepted Purchase Order as set forth herein.

8. NOTICE

Any notice, demand, or communication required, permitted, or desired to be given hereunder shall be in writing and shall be deemed to be sufficiently served for all purposes if delivered by registered or prepaid certified mail to the Parties' designated addresses provided below, or upon a Party's receipt if sent and delivered by electronic mail (email) or facsimile.

NanoVibronix, Inc.
525 Executive Boulevard
Elmsford, NY 10523

Ultra Pain Products, Inc.
23-25 31st Street
Astoria, NY 11105

9. OTHER PROVISIONS

9.1. **Relationship of the Parties.** Nothing in this Agreement shall be deemed to constitute or suggest that either Party is an agent or representative of the other party, or that the Parties are partners. Accordingly, neither Party shall (i) be responsible for acts or omissions of the other Party, (ii) have authority to speak or act on behalf of or in a representative capacity for the other Party, or (iii) obligate the other Party in any way without prior written grant of such authority from the other Party.

9.2. **Representations and Warranties.** Supplier represents and warrants that (a) all Private Labeled Products tendered under this Agreement shall be free and clear of any liens or encumbrances; (b) all Private Labeled Products shall be in conformity with the warranties set forth in **Section 6.3**; and (c) throughout the Term, Supplier shall remain in compliance with all applicable laws, regulations, and ordinances affecting the Private Labeled Products and this Agreement, including, without limitation, Supplier's obligation to maintain in good standing any applicable licenses, permissions, authorizations, consents, and permits that it needs to carry out its obligations under this Agreement. Each Party further warrants that it has the authority to enter into this Agreement and perform its respective obligations hereunder, and that executing this Agreement will not cause it to violate the terms of any preexisting obligations or agreement. Further, each Party represents that it shall obtain and maintain, for the Term of this Agreement: (a) adequate and appropriate insurance coverage; and (b) all registrations with governmental agencies, commercial registries, or any other offices which may be required under local, state, or federal laws to perform its obligations under this Agreement.

9.3. **Limitations on Liability.** With the exception of Supplier's obligations to indemnify Purchaser pursuant to **Section 9.4**, in no event shall either Party be liable to the other Party for any incidental, consequential, indirect, special, or punitive damages arising out of or relating to this Agreement, regardless of whether such liability is based on breach of contract, tort (including negligence), strict liability, breach of warranties, failure of essential purpose, or otherwise, even if advised of the possibility of such damages. Notwithstanding the foregoing, and with the exception of (a) a breach of Confidentiality as set forth herein, or (b) infringement of Supplier's intellectual property rights, each Party's total liability to the other Party shall be limited to amounts paid or payable by Purchaser to Supplier during the twelve (12) month period preceding the interposition of a claim.

9.4 **Indemnification**. Supplier shall indemnify, defend, and hold harmless Purchaser and its shareholders, officers, directors, employees, agents, affiliates, successors, and permitted assigns (collectively, "**Indemnified Party**") against any claims, actions, judgments, or expenses associated therewith, including reasonable attorneys' fees and costs, fees and the costs of enforcing any right to indemnification under this Agreement, and the cost of pursuing any insurance providers, incurred by Indemnified Party (collectively, "**Losses**"), relating to, arising out of, or resulting from:

(a) any claim of a purchaser or end-user of a Product or Private Labeled Product that arises out of or relates to the Product or Private Labeled Product, provided that such claim is not attributable to negligence, willful misconduct, or breach of this Agreement by Purchaser or a DME Distributor to whom Purchaser has sold Private Labeled Products; or

(b) Supplier's negligence, willful misconduct, or breach of its representations or warranties under **Section 9.2**).

9.5. **Force Majeure.** Neither Party shall bear responsibility of complete or partial non-performance of any of its obligations if the non-performance results from unforeseeable circumstances, such as natural calamities, fire, changes of export/import regulations or laws of any countries or territories with authority and jurisdiction, failure of transport, world or national pandemic, or any other circumstances beyond the Parties' foreseeable control. Upon such occurrence, the time for fulfillment of the Parties' respective obligations shall be extended for a period that is reasonable to accommodate the duration of the particular circumstances.

9.6. **Jurisdiction.** This Agreement shall be governed in accordance with the laws and regulations of New York, without reference to any Conflict of Laws provisions thereof. Nothing in this Agreement is to prevent a Party from brining an action for equitable or injunctive relief in a court of competent jurisdiction to compel the other party to comply with its obligations under this Agreement.

10. AGREEMENT CONSTRUCTION AND EFFECT

10.1. Incorporation by Reference. The recitals set forth above are hereby incorporated by reference into this Agreement.

10.2. Headings. The headings of this Agreement are for ease of reference only and are not intended to constitute a substantive part of this Agreement for purposes of construction.

10.3. Amendments. No amendments, modification, termination or possible waiver of any provision of this Agreement shall be valid unless provided in writing and signed by both Parties hereto.

10.4. Complete Agreement. This Agreement, including all exhibits and appendices hereto, embodies and constitutes the entire agreement and understanding of the Parties with respect to the subject matter hereof, and supersedes all prior agreements, contracts, understandings, and communications – whether oral, written, express, or implied – between the Parties relating to such subject matter, including the Original agreement. For the avoidance of doubt, the Parties' Original Agreement, amended and restated in its entirety herein, shall be deemed null, void, and of no further force or effect as of the Effective Date of this Agreement.

10.5 Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

10.6 Waiver. No waiver by any Party of any of the provisions of this Agreement shall be effective unless explicitly set forth in writing and signed by the Party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power, or privilege arising from this Agreement shall operate or be construed as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

10.7 Counterparts. This Agreement may be executed in counterparts (including electronically), each of which is deemed an original, but all of which together are deemed to be one and the same agreement.

[Remainder of Page Intentionally Blank]
Signatures to Follow*

Intending to be bound, the Parties hereto have executed this Agreement as of the Effective Date.

SUPPLIER	PURCHASER
NanoVibronix, Inc. 525 Executive Boulevard Elmsford, NY 10523	**Ultra Pain Products, Inc.** 745 Shotgun Road, Suite D Sunrise, FL 33326
By: */s/ Brian Murphy* Name: Brian Murphy Title: CEO Date: 12/9/2020	By: */s/ Ari Alayev* Name: Ari Alayev Title: President Date: _____

APPENDIX A

PRODUCTS AND PRICING SCHEDULE

PRODUCT NO.	DESCRIPTION	UNIT PRICE
10-100-0008	***PainShield® Kit:*** *PainShield® MD driver unit* *Transducer* *30 small patches* *User Manual and Quick Start* *Charger unit*	**$[***]**
10-100-0002	***Monthly Small Patch Kit:*** *1 Transducer* *30 Acrylic Patches*	$[***]
10-100-0004	***Monthly Small Patch Kit:*** *1 Transducer* *30 Silicone Patches*	***$[***]***
[TBD]	***PainShield®Plus™ Kit:*** *PainShield® MD driver unit* *2 Transducers* *60 small patches* *User Manual and Quick Start* *Charger unit*	**$[***]**
[TBD]	***Monthly Small Patch Kit:*** *2 Transducers* *60 Acrylic Patches*	$[***]
[TBD]	***Monthly Small Patch Kit:*** *2 Transducers* *60 Silicone Patches*	$[***]

**** Listed prices are in U.S. Dollars ($).***

***** Listed prices do not include applicable taxes, VAT, or freight charges.***

****** Listed prices are guaranteed through end of fiscal year 2021.***

APPENDIX B

General Warranty and Return Policy
PainShield® and *PainShield*®*Plus*^{TM}

NanoVibronix warrants that the PainShield® MD driver shall be defect-free for a period of one year from the product date of shipment.

The liability of NanoVibronix under this warranty is limited to the repair or replacement (at NanoVibronix's choice) of any allegedly defective part or parts under warranty by NanoVibronix at its expense. The defective driver shall be returned to NanoVibronix accompanied by a notice that describes the nature of the problem.

This warranty shall not apply to a product which has been subject to misuse, unauthorized use, negligence, accident, (including but not limited to fire, water, explosion, smoke, or vandalism) or which has not been operated in compliance with NanoVibronix instructions of use.

Without derogating from the above, this warranty is void, if at any time anyone other than NanoVibronix authorized personnel removes the product casing and/or attempts to make any internal changes, removals, attachments or additions to the product or its components.

Sheaths/patches used with the PainShield® MD driver are not covered by this warranty, as they are warranted as suitable for intended use. No warranty of use applies to sheaths/patches upon first application.

APPENDIX C

Table 1

Effective Date of Agreement → End of Fiscal Year 2021

DESCRIPTION	Q1	Q1	Q1	Q1	TOTAL
*Private Labeled Product*** Kit*	1,250	1,250	1,250	1,250	**5,000**

Table 2

Fiscal Year 2022

DESCRIPTION	Q1	Q2	Q3	Q4	TOTAL
Private Labeled Product Kit*	2,500	2,500	2,500	2,500	***10,000***

Table 3

Fiscal Year 2023

DESCRIPTION	Q1	Q2	Q3	Q4	TOTAL
Private Labeled Product Kit*	2,500	2,500	3,000	3,000	**11,000**

Table 4

Renewal Term(s)

DESCRIPTION	Q1	Q2	Q3	Q4	TOTAL
Private Labeled Product Kit*	3,000	3,000	3,000	3,000	**12,000**

*** *Private Labeled Product*** denotes one or more Products as identified in Appendix A.

Purchaser's yearly and quarterly minimum order quotas (Tables 1-4) may be satisfied by units of the *PainShield*® Kit, *PainShield*®*Plus*™ Kit, or any combinations thereof.

Pricing of Purchaser's orders will be determined based on the Product (i.e., PainShield® or PainShield®*Plus*™ and the units thereof, or of each if a combination is desired.

APPENDIX D

Pursuant to the appended Agreement entered into by the Parties on this ___ day of December, 2020, and as specifically provided in **Section 3.12** thereof, Purchaser hereby acknowledges its obligations and assumed liability for any DME Distributors to whom it sells Products or Private Labeled Products adhering to and complying with:

(a) limitations on pricing of Private Labeled Products, and specifically on publicized pricing of any kind, as set forth in **Section 3.5** of the Agreement;

(b) all sales of Private Labeled Products being limited to the Territory, as set forth in **Section 3.6** of the Agreement;

(c) the prohibitions against any modifications of the Private Labeled Products, as set forth in **Section 3.7** of the Agreement;

(d) Supplier's limited warranty with respect to any Private Labeled Products, as set forth in **Section 3.8** of the Agreement;

(e) Any applicable FDA requirements for obtaining physician prescriptions as a prerequisite to selling Private Labeled Products, including Supplier's PainShield® device, to customers and maintaining records thereof, as set forth in **Section 3.9** of the Agreement;

(f) the reporting obligations set forth in **Section 3.10** of the Agreement, and supplying complete reports to Supplier on at least bi-annual basis; and

(g) the duty of confidentiality set forth in **Section 3.11** of the Agreement.

Executed on even date herewith by and on behalf of:

Purchaser

Ultra Pain Products, Inc.
745 Shotgun Road, Suite D
Sunrise, FL 33326

By: _____
Name: Ari Alayev
Title: President

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of NanoVibronix Inc. on Forms S-3 File Nos. 333-229106, 333-236000, 333-239965 and 333-251264) and Form S-8 (File No. 333-205577) of our report, dated April 15, 2021, with respect to our audits of the consolidated financial statements of NanoVibronix Inc. and Subsidiaries as of December 31, 2020 and 2019 and for each of the two years in the period ended December 31, 2020 which report is included in this Annual Report on Form 10-K of NanoVibronix Inc. for the years ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
New York, NY
April 15, 2021

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)

I, Brian Murphy, certify that:

1. I have reviewed this Annual Report on Form 10-K of NanoVibronix, Inc. (the "registrant");

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: April 15, 2021

By: */s/ Brian Murphy*
Name: Brian Murphy
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)

I, Stephen Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K of NanoVibronix, Inc. (the "registrant");

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: April 15, 2021

By: */s/ Stephen Brown*
Name: Stephen Brown
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the year ended December 31, 2020 of NanoVibronix, Inc. (the "Company"). I, Brian Murphy, the Chief Executive Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: April 15, 2021

By: */s/ Brian Murphy*
Name: Brian Murphy
Title: Chief Executive Officer (Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-K for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

EXHIBIT 32.2

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the year ended December 31, 2020 of NanoVibronix, Inc. (the "Company"). I, Stephen Brown, the Chief Financial Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: April 15, 2021

By: */s/ Stephen Brown*
Name: Stephen Brown
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-K for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.