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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from to

Commission File Number: 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 ☒

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of our common stock held by non-affiliates as of June 30, 2022, was approximately $17,539,360.

The number of shares outstanding of the registrant's Common Stock as of April 17, 2023 was 1,662,377 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 2023 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.

NANOVIBRONIX, INC.

2022 ANNUAL REPORT

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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 risks 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.
- Global economic and political instability and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business, financial condition or results of operations
- Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows.
- 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 ("FDA") 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.
- 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.
- 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, which has been marketed in the U.S. under FDA's policy of enforcement discretion during the COVID-19 pandemic and is currently undergoing clinical testing that will, hopefully, support 510(k) clearance;

- 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. Our PainShield family of products include:

    - PainShield™ MD, a single 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.

    - PainShield™ Plus, a dual 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. Similar to PainShield MD, it has a dual ultrasound delivery; 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™, MD is currently cleared for marketing in the United States by the U.S. Food and Drug Administration ("FDA"). In September 2020, the FDA exercised its Enforcement Discretion to allow distribution of the UroShield device in the U.S. during the COVID-19 health emergency. While the permitted use is currently temporary, it does permit the import of the UroShield to the U.S. during the ongoing COVID-19 pandemic. Our understanding is that this permitted use will be terminated six months after the health emergency is officially ended. All three of our products have CE Mark approval in the European Union, and a certificate allowing us to sell PainShield and UroShield in Israel. We are able to sell PainShield and UroShield in India and Ecuador based on our CE Mark. We have consummated sales of PainShield and UroShield in the relevant markets, and we saw sales increase in 2021, but decline slightly in 2022. 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 require a prescription from a licensed healthcare practitioner. If FDA clearance is obtained, we anticipate that WoundShield will require a prescription from a licensed healthcare practitioner in the United States. As stated previously, UroShield has been approved through the FDA under Enforcement Discretion for the duration of the Covid-19 health emergency and is intended to be sold directly to health care facilities and individuals. Individuals will require a prescription but healthcare facilities will deploy based upon clinical need. 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 and PainShield, 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. However, the company continues to work toward a reimbursement value from CMS. We are working with qualified legal representation toward that goal. The company was denied reimbursement in September 2022 due to a lack of "life-cycle" testing. The company has engaged Carmel Labs in Israel to conduct this testing. We are approximately 85% of the way through this testing, with all devices working properly. In January 2023, we submitted another application to CMS with "life-cycle" testing pending. Along with our application, we submitted an interim report which was positive in nature. The latest CMS application will include both PainShield and UroShield products and supplies. 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 a reimbursement expert, the law firm of Brown and Fortunato as regulatory counsel, to help facilitate our applications, potentially leading to reimbursement.

We have completed seven separate clinical studies with UroShield that together evaluated approximately 220 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 skilled nursing facilities 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 and distributors for sales and marketing efforts in the United States. The Company has entered into recent distribution partnerships for UroShield in the U.K., Australia, and Malta.

We have one clinical study recently completed for our product UroShield. We announced positive interim results from an independent, real world patient study of UroShield at Southampton University Health Sciences in December 2021. The independent study, which was launched in the first half of 2021, was devised to evaluate how UroShield helps to reduce infection by preventing bacteria colonization and the buildup of biofilms on long-term indwelling urinary catheters in real world patients and to better understand the patient benefits and experiences of using UroShield. The study consists of both laboratory and patient studies and is nearing completion. At the conclusion of the study, Southern Health reported a significant reduction in catheter blockage and a positive effect on the microbiome. Full results of the study are expected to be published in 2023.

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 included the 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.

We are currently in advanced negotiations with a major teaching medical university to conduct a study on UroShield, which is intended to satisfy the FDA requirements for traditional 510k clearance. We expect that study to commence in either the third or fourth quarter of 2023.

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

- 91% of the patients in the PainShield treatment group had complete or partial resolution of symptoms. Patients used PainShield in conjunction with over-the-counter medication, as needed, but without the benefit of opioid-based prescription medication.

We believe results of the Birmingham study could further reinforce that PainShield is safe, easy-to-use and highly effective in treating soft tissue pain. Patients in the study who wore our device reported marked reduction in pain and when combined with over-the-counter, anti-inflammatory medications, those same patients reported a complete resolution of symptoms within 10 days.

Dr. David Lemak, MD, Lead Investigator of the Birmingham Study, added, "Patient outcomes were markedly improved with the use of PainShield and importantly, no patients returned with signs or symptoms of an exacerbation. Most encouraging are the results we were able to achieve for our patients without the use of prescription opioid medications, which can often lead to prolonged use and addiction."

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.

Recent Developments

On March 21, 2023 we announced that we filed a new provisional patent application with the United States Patent and Trademark Office ("USPTO") entitled "Multiple Frequency Surface Acoustic Waves for Internal Medical Device" (the "Patent Application") related to its UroShield. The Patent Application covers a recently developed enhancement to the UroShield product, UroShield "Ultra", which incorporates improvements to the Company's original UroShield. The next generation UroShield Ultra includes modified housing that is designed to improve catheter coupling and incorporates multiple actuators that work in sequence to discourage bacterial docking by delivering SAWs at multiple frequencies directly to indwelling catheters.

On March 15, 2023 we announced the positive evaluation results for our UroShield device, presented at a recent medical conference by clinicians from the Royal National Orthopaedic Hospital ("RNOH"). The report concluded that our UroShield device showed a decrease in the number of blockages and infections and an increase in catheter satisfaction in the patients studied. In addition, evaluators concluded that the device has the potential to improve quality of life and reduce healthcare associated costs for patients with spinal cord injuries who experience recurrent blockages or infections and who have complicated catheter issues.

In April 2022, we announced that UroShield was approved for sale by NHS Supply Chain through a new contract. This new contract with NHS Supply Chain provides a dedicated end-to-end supply chain service of our UroShield for every NHS healthcare organization. UroShield will be available to all patients who need the device with full clinical support, through the NHS supply chain. On September 23, 2022, UroShield was approved for sale by the NHS Supply Chain through a new contract. The new contract, which is designed to provide new innovative products for healthcare providers, begins in October 2022 and will merge with the existing Urology and Stoma framework contract in February 2024 with optional extension periods.

PainShield was granted a dedicated reimbursement code (K1004) by CMS in 2021, which was an initial step towards paving the way for many millions of beneficiaries enrolled in Medicare to have access to our product. In addition, CMS expanded its reimbursement approval of the company's PainShield™ product by adding the device to its Durable Medical Equipment (DME) schedule. ricing was not established at that time, and our efforts to obtain favorable pricing resulted in a denial, pending further testing of the device's life expectancy. Testing to gather life expectancy data began in October 2022, and we are preparing to demonstrate the life expectancy in the next few months. We are hopeful of a positive outcome that will allow us to secure pricing and remove the barriers for distribution to beneficiaries under Medicare.

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 vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, although denied all Protrade's claims, nevertheless awarded Protrade about $1.5 million, on the grounds that the Company allegedly failed to fulfill an order for reusable hydrogel patches placed after the Agreement was terminated. The arbitrator based her decision on the basis of testimony of Protrade's president who asserted that a patient would use in excess of 33 reusable patches per each device, which the Company believes is a grossly inflated number.

On April 5, 2022, Protrade filed a Petition with the Supreme Court of New York Nassau County seeking to confirm the Award. On April 13, 2022, the Company submitted an application to the ICA seeking to correct an error in the award based on the evidence that the Company only sold 2-3 reusable patches per device contrary to the 33 reusable patches claimed by Protrade. The same arbitrator who issued the award, denied the application.

On July 22, 2022, the Company filed a cross-motion seeking to vacate the arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the Award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newel information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the Court denied the motion to re-argue and renew. The Company intends to file a notice of appeal with the Appellate Division, Second Department and to continue to vigorously pursue its opposition to the award in all appropriate fora. As of December 31, 2022, the Company accrued the amount of the award to Protrade amounting to $1,846,794 with $1,500,250 as part of "General and administrative expenses" and $346,544 as part of "Interest expense", and the full amount included in "Other accounts payable and accrued expenses".

Business Model

All of our products consist of a reusable controller device and a disposable component, which includes a transducer, and in the case of PainShield, a 30 day supply of adhering patches. The controllers have a life expectancy of three years, while the UroShield 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 disposables to the extent that the end user continues treatment with our product.

Our products are intended to be distributed directly by the company, independent distributors, and 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 are in the process of adding additional distributors to our network, and continue our efforts to identify market leaders in various segments to private label both PainShield and UroShield.

We also have a direct sales component, where we sell directly to consumers, in order to satisfy customer demand generated through on-line advertising and social media. We have seen an increase in demand as a direct result of an expanded social media and on-line advertising presence.

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

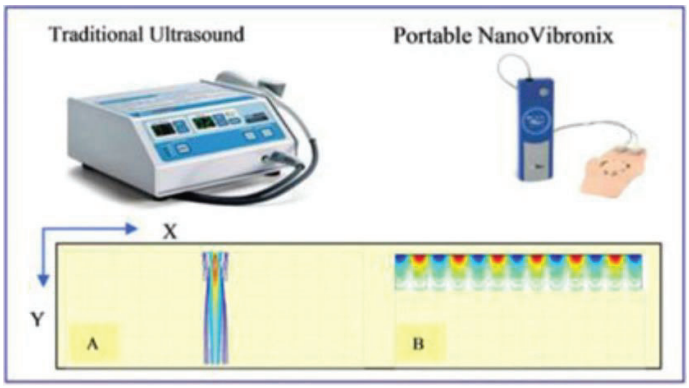
As noted above, our primary products are based on the use of low frequency ultrasound, which delivers energy through mechanical vibrations in the form of sound waves. Ultrasound has long been used in physical therapy, physical medicine, rehabilitation and sports medicine.

Our proprietary PainShield 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 pain 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 may provide a competitive advantage over other existing therapies marketed for similar intended use(s) (e.g., to treat pain associated with muscle, tendon, and contractures), as our technology is positioned to directly target the affected areas of the body within the scope of the applicable FDA clearance.

While there are currently a number of products on the market that treat pain through ultrasound therapy, we believe that our products may be preferable in certain instances 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 closer to 1MHz and above), which means our products, when functioning as intended and in accordance with applicable design specifications, should not produce excessive 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 also aware of one product, the SAM® Sport family of products, which received FDA approval and 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 FDA has issued contraindications which do not apply to the PainShield product.

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 soft tissue 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.



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.

The PainShield Plus was introduced in March 2022. The new product design provides the same therapy as PainShield MD, but through two transducers which alternate in its duty cycle. This dual transducer design provides for a broader treatment are with three hours of therapy.

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

In a 2007 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).

Relative to soft tissue repair, 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. 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.

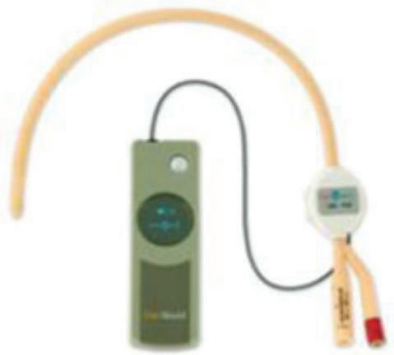
Our Products

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 manufacturing in China, Singapore, and Israel 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. Use of the device is contraindicated for use while there is an active Urinary Tract Infection. 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 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

Clinical studies of the UroShield system have supported 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.

In September 2022, UroShield was approved for sale by the U.K.'s National Health System's (NHS) internal supply organization, NHS Supply Chain, through a new contract.

This new contract with NHS Supply Chain provides dedicated end-to-end supply chain service of our UroShield for every NHS healthcare organization. UroShield will be available to all patients who the need the device with full clinical support, through the NHS supply chain. It represents a significant opportunity for us to expand distribution of UroShield as it will now be made available to all clinicians and their patients through the NHS organization's own supply channel. NHS Supply Chain manages the sourcing, delivery and supply of healthcare products and services for NHS trusts and healthcare organizations across England and Wales. The organization processes more than eight million orders per year across 94,000 order points and 17,465 locations serving as an integral part of the national healthcare system in the U.K. We are ramping up production to meet an increase in demand that we anticipate as a result of this exciting development.

The new contract, which is designed to provide new innovative products for healthcare providers, begins in October 2022 and will merge with the existing Urology and Stoma framework contract in February 2024 with optional extension periods.

Under the contract, NHS Supply Chain describes UroShield as a disposable ultrasound device designed to reduce the risk of catheter-associated urinary tract infection (CAUTI) by reducing bacterial colonization and biofilm formation on indwelling urinary catheters. This ultimately translates into improved outcomes for patients and care provides, reduces the need for antibiotics, catheter changes and washouts and incidence of hospital visits, thereby reducing nursing time, bed days and ambulance transfers.

On March 1, 2023 the Company launched its month-to-month rental program for UroShield.

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. However, in the United States, we do not have the requisite regulatory authorization to market UroShield for such use, as we have not yet obtained FDA clearance or approval for UroShield, and the FDA's temporary, COVID-19-related policy of Enforcement Discretion under which we have been marketing UroShield since September 2020 expressly excludes use with a coated catheter. 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 was temporarily authorized for use in the United States per FDA's Enforcement Discretion during the COVID-19 health emergency, the public health emergency has since-been terminated, and the applicable FDA policy under which we have been marketing UroShield will similarly terminate before the end of 2023. In particular, recent FDA guidance confirmed that its medical-device enforcement policies issued during the COVID-19 pandemic will officially expire on November 7, 2023. The guidance outlines a three-phase plan for ensuring that any devices marketed under a specifically listed enforcement policy will be able to be marketed lawfully after the termination of those enforcement policies. During the 180-day period between the termination of the public health emergency and the expiration of FDA's relevant enforcement policies, manufacturers, like us, who desire to continue marketing their respective devices must submit an appropriate premarket submission, such as a 510(k) application or *de novo* reclassification request, and bring the device into compliance with applicable FDA regulations. If we do not obtain permanent clearance from the FDA by November 7, 2023, we will have to discontinue distribution of UroShield in the United States until the necessary FDA clearance or approval is granted. We cannot guarantee that FDA will clear or approve UroShield for continued marketing in the United States in a timely manner or at all.

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 or around October 2022.

In the European Union, UroShield has been marketed for the prevention of CAUTI and biofilm formation, 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 temporarily cleared 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, which will officially end in November 2023. The device is designed to aid in the prevention of CAUTI incidence in patients requiring long-term indwelling catheterization, defined as 14 days or greater.

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. We believe 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.

We intend to seek long-term marketing authorization from the FDA through the *de novo* classification process for UroShield, which is a premarket pathway intended for devices that cannot pursue 510(k) clearance because there is no substantially equivalent predicate device but which the applicant believes are sufficiently low-risk that they need not undergo the rigorous premarket approval pathway to be deemed safe and effective for the applicable indications for use. We are currently seeking advice from the FDA prior to submission. We also intend to seek advice and validation of supporting studies we intend to undertake in advance of a De Novo application.

The FDA has made it clear that we will need to generate more clinical study data in order to achieve) de novo reclassification. Our intent is to conduct a community based PRO study (Patient Reported Outcomes) measuring the impact UroShield will have on prevention of CAUTI, Prevention of Blockage, and prevention of Pain. We currently are in the early stages of putting together a team and plan to start this process.

Studies completed to assess the 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 marketing authorization from the FDA, is recognized as effective and becomes widely adopted for use on catheters, none of which can be guaranteed. 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. Malta, and Australia. We recently appointed the Benion group to identify distributor opportunities outside of the United States.

We announced in December 2022 that we have appointed a new distributor in the United Kingdom. The newly appointed distributor is Peak Medical.

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. There has also been interest from other companies with various invasive line applications.

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.
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	Dr. Shira Markowitz Buffalo, NY	2017 55 patients	To demonstrate the use of the UroShield	Final results entitled "The Effect of Surface

Purpose	Doctor/Location	Time, subjects	Objectives	Results
Study for Prevention of Bacterial Colonization and UTI associated with Indwelling Urinary Catheters			reduces bacterial colonization on the urinary catheter	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). 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

Purpose	Doctor/Location	Time, subjects	Objectives	Results
				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.)
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

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 FDA Administration trial ~300 patient trial	To be determined	To be determined Intended to begin in 2023	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.

We believe 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. Some patient benefits reported in prior studies included ease of application and use, relatively quick recovery time, high patient compliance, and potentially increased safety and efficacy over certain other 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

In other countries outside the United States where the product is approved for such use, 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. In the United States, PainShield is only cleared to treat pain, muscle spasms, and joint contractures associated with or caused by various conditions or diseases. It has also been used to treat pelvic and abdominal pain. To date, to the best of our knowledge, the primary treatment options for several of 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.

On March 1, 2023 the Company launched its month-to-month rental program for Painshield.

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 FDA 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 FDA has issued contraindications which do not apply to the PainShield product. 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.

CMS has approved PainShield for reimbursement for Medicare beneficiaries on a national basis effective January 2020, we are currently awaiting reimbursement values to be determined. We will be notified in May 2023. A positive determination would become effective on October 1st, 2023. If we are denied, the appeal process would begin in June 2023.

Our marketing efforts continue to expand in the Direct to Consumer, Veterans Administration facilities, and Workers' Compensation market. Relative to the VA market, we are currently represented by Applied Medical and Delta Medical. Delta Medical is a Service Disabled Veteran Organization Small Business (SDVOSB). PainShield is approaching the Workers' Compensation market through various sales agents and on a direct basis. Additionally, on March 1st, 2023, we established a rental program for Direct to Consumer marketing for patients without health insurance coverage.

Regulatory Strategy

PainShield received 510(k) clearance from the FDA in August 2008 as an ultrasonic diathermy device intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions, such as relief of pain, muscle spasms, and joint contractures. 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.

In the United States, a prescription from a licensed healthcare practitioner is required for the use of PainShield.

Recently, we announced our intention to pursue marketing authorization for a non-prescription version of PainShield MD, which we refer to as PainShield Relief. The PainShield Relief is intended to be an Over-The Counter (OTC) product, not requiring a prescription from a medical professional. We believe that such reclassification, if approved by the FDA, 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 Relief or that, even if we accomplish such reclassification and the use of PainShield Relief no longer requires a prescription, PainShield Relief 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 prove to the FDA that the requirement for a physician prescription is not necessary to ensure safe and effective use of the product, proof of safety and consumer "usability" need to be established. We engaged User-View, Inc to facilitate our Usability study and received the favorable results we expected. The product packaging and all instruction documents have been modified in an effort to meet OTC standards. We also engaged an outside laboratory to perform acoustic testing on all PainShield products. We previously anticipated submission of a 510(k) for PainShield Relief to the FDA, for OTC use as a class 1 device, in early April 2022, but we are reconsidering our target timeline for such submission and whether any additional data or action steps are needed including potentially redesigning the product in appearance and functionality.

The PainShield Plus, is a dual applicator device, which will also be submitted for specific clearance from the FDA. Submission for PainShield Plus was made in late February 2022. We received FDA clearance in November 2023.

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 continue to work 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. We have engaged outside legal counsel to assist with all aspects of reimbursement and FDA regulatory actions. In addition, we intend to conduct clinical trials in order to pursue FDA authorization to 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, depending on the scope of the approval or clearance from each applicable jurisdiction, and we have sold over 5,000 units since its introduction. We have entered into distribution agreements in United States, Europe, Australia, 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 in jurisdictions where direct-to-consumer sale is permitted. 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 application for PainShield in applicable foreign jurisdictions where such application is authorized, which is the treatment of a severe facial nerve pain called Trigeminal Neuralgia, otherwise known as tic douloureux. The FDA lists facial application as a contraindication and has not cleared or approved PainShield for such use in the United States. We are considering pursuing FDA approval of the PainShield for Trigeminal Neuralgia, which will likely require additional data and clinical investigation to support an application for premarket approval ("PMA") for this indication, if such PMA is required by FDA. 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 could prove to be a practical and safe alternative. A broader RCT, targeting 60 patients suffering from unilateral trigeminal neuralgia, was also 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". We cannot predict the success of any future trials, nor can we guarantee that FDA will grant approval for such use.

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 in the foreign jurisdictions where PainShield has been approved 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.
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	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.

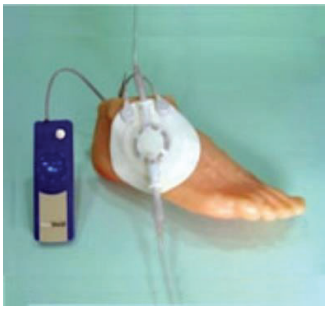
Purpose	Doctor/Location	Time, subjects	Objectives	Results
			●To assess the injury status ●To assess the efficacy of the treatment ●To assess compliance factors	Lack of funding for statistical analysis has stopped this trial prior to fulfillment.
Reduction of chronic abdominal and pelvic pain, urological 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 FDA and other regulatory agencies around the world.

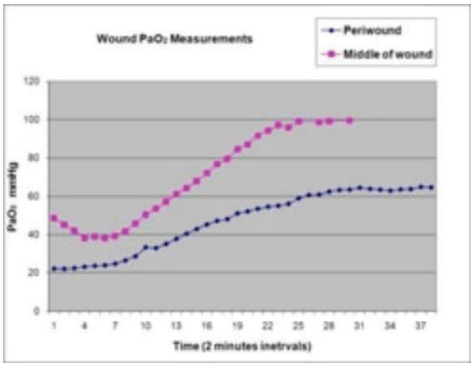


Picture of WoundShield Driver and Instillation Patch

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 $20.8 billion in 2022 and it is expected to grow to $27.2 billion by 2027 at a CAGR of 65.4% during 2022-2027 (as reported by Markets and Markets in June 2022). 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 FDA , 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 FDA 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 to allow our licensee to pursue FDA clearance. To date, SanuwaveHealth, Inc. has not met their contracted milestones to retain the license for WoundShield.

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

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 FDA for commercial distribution, we may find limited demand for the device until adequate reimbursement has been obtained from governmental and private third -party payers.

Over-the-counter products, such as the anticipated PainShield Relief product that we are developing, if ultimately cleared for marketing by the FDA, are generally not reimbursed by any 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. If cleared or approved by the FDA for the U.S. market, 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. We continue to work toward a favorable reimbursement with outside legal counsel and reimbursement consultants. The most recent application for reimbursement from CMS/Medicare was submitted on January 3rd, 2023. A determination should be provided in or around May 2023.

WoundShield. We believe that the initial usage of these products, if approved or cleared by the FDA, 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. Sanuwave Health Inc., as the licensee of this technology, is responsible to apply for such reimbursement, but has not yet done so.

New Product Under Development

Renooskin

In 2016, we started developing a device candidate 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, neither of which are guaranteed, the device candidate could potentially 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 and have adopted a more fully 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.

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Patents

We seek patent protection for our inventions not only to differentiate our products and technologies, but also to develop opportunities for licensing and securing our rights to profits therefrom. With the aim of optimizing commercial and regulatory success, our proprietary technology and innovative applications thereof are protected by a variety of patent claims. We believe that our granted patents and pending applications collectively protect our technology, both in terms of our existing products, as well as our anticipated pipeline of new offerings.

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 and for wound healing, and for preventing formation of bacterial biofilms on catheters.

In addition to the above patents, our pending patent applications and new filings are representative of our ongoing efforts to broaden our portfolio as we continue to develop new applications for our ultrasound technology. Pending patent applications related to UROSHIELD® devices are directed to *Multiple Frequency Surface Acoustic Waves for Internal Medical Device* and *System, Device, and Method for Mitigating Bacterial Biofilms Associated with Indwelling Medical Devices*. Ths new patent applications cover the next generation of UROSHIELD® devices operating at multiple frequencies and devices which are compatible in portable and wireless systems.

Pending patent applications related to PAINSHIELD®, PAINSHIELD PLUS™, WOUNDSHIELD® devices are directed to *Transdermal Patch of a Portable Ultrasound-Generating System for Improved Delivery of Therapeutic Agents and Associated Methods of Treatment*; *Portable Ultrasound System and Methods of Treating Facial Skin by Application of Surface Acoustic Waves* and *Improved Injection Needle Assembly*.

Although not yet granted, the aim of our growing number of patent applications is to secure our rights within additional industry sectors we foresee as most readily benefiting from our technology. Therefore, looking beyond just pain management and urology, our patent applications relate to, *inter alia:* novel transdermal patches uniquely configured to work with our ultrasound technology to additionally provide for improved absorption and transdermal delivery of therapeutic agents during treatment; cosmetic applications of our ultrasound technology to provide anti-aging benefits; and certain new or improved stand-alone therapeutic medical devices or so-called "indwelling medical devices" (e.g., catheters, intravenous (IV) needle assemblies, and percutaneous endoscopic gastronomy (PEG) tubes) that include our SAW-generating technology to provide the accompanying antimicrobial effect for preventing infections typically associated with available indwelling devices.

We intend to further grow our patent portfolio by continuing to patent new technology as it is developed, to defend intellectual property as we believe necessary by actively pursuing any infringements, to pursue commercial opportunities our patents provide for our innovations, and to continue to develop our brands and trademarks.

Trademarks

In addition to patent protection, we own numerous registered trademarks for our commercialized WOUNDSHIELD® (in the U.S. and Canada), 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 ("FDA") before they can be marketed in the United States, and they can only be marketed consistently with their respective approved or cleared indication(s) of use. 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 FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. The FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, distribution and market withdrawal and recalls of medical devices and pharmaceutical products. PainShield MD and PainShield MD Plus have each already obtained 510(k) marketing clearance by the FDA. We are in the process of conducting clinical and non-clinical testing to support a submission for FDA clearance for PainShield Relief as an over-the-counter drug.

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 temporarily cleared the way for import of UroShield to the U.S. for limited use during the Covid-19 pandemic. The public health emergency has since-been terminated in the U.S., and the FDA, accordingly, issued guidance confirming that devices marketed under Enforcement Discretion must be cleared or approved by November 2023 to remain on the market. The fact that FDA authorized UroShield's use under the COVID-19 Enforcement Discretion does not ensure that UroShield will be granted marketing approval or clearance under any of the traditional pathways.

FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls FDA 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. Due to its nature and the lack of existing predicate devices on the market, UroShield is automatically classified as a Class III device for which a PMA is required, *unless* our request for *de novo* reclassification is successful, in which case, it will be classified as a Class II device and subject to the same postmarket framework as 510(k)-cleared devices.

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 a legally marketed medical device (referred to as a "predicate device"). A finding of substantial equivalence requires that the proposed new device (i), has the same intended use as a predicate device; (ii) has the same or similar technological characteristics as the predicate device; (iii) is as safe and effective as the predicate device; and (iv) does not raise different questions of safety and effectiveness than the predicate device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. 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 guarantee that the timing will not be longer.

The FDA 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 FDA determines that the product does not qualify for 510(k) clearance, then a company must submit and the FDA must approve a PMA before marketing can begin. An alternative to a new 510(k) submission is a "letter to File", citing substantial equivalence to a product which has been granted 510(k) clearance.

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 FDA will inspect the manufacturer's facilities for compliance with quality system regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, a FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances where the FDA has not. If the FDA finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. 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 we will seek FDA authorization to market our UroShield product via the de novo reclassification process. Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they ultimately pose to patients and/or users. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II based on a benefit-risk analysis demonstrating the device actually presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low-to-moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. *De novo* reclassification requests are also subject to user fees, unless a specific exemption applies. 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

Clinical trials are almost always required to support a PMA application and are sometimes required for a de novo classification request or 510(k) pre-market notification. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, an investigator acting on behalf of the company must, among other things, apply for and obtain IRB approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the company sponsoring the investigation must also submit and obtain FDA approval of an IDE. An IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of study participants, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE is approved by the FDA and the study protocol and informed consent are approved by a duly-appointed IRB at each clinical trial site.

FDA's IDE regulations govern investigational device labeling, prohibit promotion, and specify an array of GCP requirements, which include, among other things, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

Post-Approval Regulation of Medical Devices

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

- the FDA quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;

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

- if applicable, the Electronic Product Regulations found in 21 CFR parts 1000-1050, which provide additional requirements applicable to electronic products, including records and reporting requirements; and

- the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experiences associated with use of the product.

Under the FDA medical device reporting ("MDR") regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any distributed devices fail to meet established specifications, are otherwise misbranded or adulterated, or if any other material deficiency is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

The failure to comply with applicable device regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA approvals of new products;
- withdrawals of marketing authorization; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors and third-party component suppliers

Good Manufacturing Practices Requirements

As noted above, 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 FDA 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 FDA and other authorities to assess compliance with applicable regulations. Failure to comply with or to promptly 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 FDA and could result in the imposition of marketing restrictions through labeling changes or in product recall. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

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

Quasar added a new manufacturing facility in Singapore late in the third quarter of 2022. Our product manufacturing moved to this plant for final production and packaging.

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 B Star, Inc, Plastic One, 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 99% of our sales coming through distributors and Sales Agents in 2022. We expect that percentage to decline as we enter into additional sales agent 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. For the year ended December 31, 2022, our two largest customers were Applied Medical Solutions LLC who comprised approximately 44% of total sales and Ultra Pain Products Inc, who comprised approximately 36% of total sales.

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, 2022, we had 9 full-time employees and 5 part-time employees, which is a decrease from the 12 full-time employees and an increase of one-part-time employee we had as of December 31, 2021, and as of March 31, 2023, we have added one additional full-time employee in 2023. 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 and 2021, 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
- Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows.
- The ongoing COVID-19 pandemic has and may continue to adversely impact our business.
- 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.
- 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 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.
- We face the risk of product liability claims and may not be able to obtain insurance.
- Our product candidates may not be developed or commercialized successfully.
- 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 need to increase the size of our organization in order to successfully manage our growth.
- Our failure to protect our intellectual property rights could diminish the value of our solutions, weaken our competitive position and reduce our revenue.
- 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.
- We face risks associated with litigation and claims.
- The Company's financial statements have been prepared on a going concern basis, and do not include adjustments that might be necessary if the Company is unable to continue as a going concern. Management has substantial doubt about the Company's ability to continue as a going concern.
- Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

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 and after approval or clearance and during the marketing of our products.

- UroShield has not been cleared or approved by the FDA, nor has it undergone the same type of review as an FDA-approved or cleared device.
- Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.
- We are uncertain regarding the success of our clinical trials for our products in development.
- We depend on Sanuwave for developing and commercializing our WoundShield technology.
- Healthcare reform measures could adversely affect our business and financial results.
- 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.

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

Risks Related to Our Organization and Our Securities

- The price of our securities may be volatile, and the market price of our securities may drop below the price you pay.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- We may be subject to ongoing restrictions related to grants from the Israeli 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**.**
- Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.
- If we fail to maintain effective internal control over financial reporting, our business, financial condition or results of operations may be adversely affected.

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, 2022 we had a net loss of approximately $5.4 million, with revenues of approximately $0.8 million. As of December 31, 2022, we had an accumulated deficit of approximately $62.4 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 ("FDA") 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.

Global economic and political instability and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions and geopolitical conflicts, such as the conflict between Russia and Ukraine. While we do not have any customer or direct supplier relationships in either country at this time, the current military conflict, and related sanctions, as well as export controls or actions that may be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.) and other potential uncertainties could adversely affect our business and/or our supply chain, business partners, employees or customers, and interrupt our ability to supply products, or otherwise adversely impact our business.

Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows.

Inflation, as well as some of the measures taken by or that may be taken by the governments in countries where we operate in an attempt to curb inflation may have negative effects on the economies of those countries generally. If the United States or other countries where we operate experience substantial inflation in the future, our business may be adversely affected. This could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Specifically, our existing distributor agreements limit the amount that we can increase the price that we sell our products to the distributors. Accordingly, an inflationary environment, including factors such as increasing freight and materials prices, could make it less profitable for us to do business.

The ongoing COVID-19 pandemic has and may continue to adversely impact our business.

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 had compelled us to furlough or reduce working hours for much of our operating staff in 2020, and continue to force remaining staff as well as third-party contractors, to work remotely from time to time. 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 commercial 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 FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- 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 nine full-time employees and five 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 in order to 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 patents, as well as pending patent applications, in both the United States and relevant 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 or that our patents would prevent a competitor from designing around our claims in our patents. 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.

We have granted US issued patents, as well as issued patents in Europe and China and a number of corresponding foreign patents in other relevant jurisdictions, covering UROSHIELD® devices and have expiration dates ranging from May of 2023 to July of 2030. We also have pending patent applications related to UROSHIELD® devices, which would have expected expiration dates, if granted, ranging from December of 2041 to March of 2044.

Granted patents related to PAINSHIELD®, PAINSHIELD PLUS™, WOUNDSHIELD® have expiration dates of August of 2033 in the United States, and February of 2027 in Europe, China and Israel. We also have pending patent applications related to PAINSHIELD®, PAINSHIELD PLUS™, WOUNDSHIELD® devices, which would have expected expiration dates, if granted, ranging from September of 2040 to December of 2041.

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 as 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.

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. While the Company has vigorously defended the claims asserted by Protrade, the litigation is ongoing and we may be subject to other lawsuits, claims, or proceedings. See "Item 3. Legal Proceedings – Protrade Proceeding" for a full description of the Protrade proceeding.

The Company's financial statements have been prepared on a going concern basis, and do not include adjustments that might be necessary if the Company is unable to continue as a going concern. Management has substantial doubt about the Company's ability to continue as a going concern.

The Company's consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. During the year ended December 31, 2022, the Company's cash used in operations was $7,035 leaving a cash balance of $2,713 as of December 31, 2022. Because the Company does not have sufficient resources to fund our operations for the next twelve months from the date of this filing, management has substantial doubt of the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company will need to raise additional capital to finance its losses and negative cash flows from operations and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability. There are no assurances that the Company would be able to raise additional capital on terms favorable to it. If the Company is unsuccessful in commercializing its products and raising capital, it will need to reduce activities, curtail, or cease operations.

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 and after approval or clearance and during the marketing of our products.

The process of obtaining FDA 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 FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected.

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 FDA approval and clearance, or FDA refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- 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 (including the prohibition on promoting devices for "off-label" uses);
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with the use of the products, as well as our discovery of defects or a product's failure to comply with design specifications or applicable law; and
- obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

We are also subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We also cannot be sure that the FDA will agree with our analysis of, conclusions regarding, or handling of various situations that arise with our products. If it is determined that we failed to comply with any of our regulatory obligations, we could be subject to a wide range of enforcement actions that could limit our ability to continue to successfully commercialize impacted products or otherwise adversely impact us.

The FDA'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.

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

In September 2020, the 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. government has since-terminated the public health emergency, and FDA recently confirmed via guidance that the applicable policy of Enforcement Discretion under which UroShield was maketed during the pandemic will expire in November 2023. Accordingly, if we do not obtain FDA approval or clearance by the expiration of the applicable Enforcement Discretion policy in November 2023, we will have to discontinue distribution of UroShield in the U.S. until FDA grants the requisite premarket authorization, which may not occur in a timely manner, if at all. 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 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 FDA 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 novel lines of product candidates 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 FDA 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 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 over a decade. However, as of the Supreme Court's ruling ordering the dismissal of, arguably, the most promising case challenging the Affordable Care Act to-date in June 2021, it appears that the Affordable Care Act will remain in-effect in its current form for the foreseeable future. We cannot predict what additional challenges to the Affordable Care Act may arise in the future, the outcome thereof, or the impact any such actions may have on our business. Additionally, the Biden administration has introduced various measures in recent years, focusing on healthcare and medical-product pricing, in particular. It remains to be seen how these measures will affect our business and there is uncertainty as to what other healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S., but it is possible that such initiatives could have an adverse effect on our ability to obtain FDA approval or clearance and/or successfully commercialize products in the U.S. in the future. For example, any changes that reduce, or impede the ability of healthcare providers to obtain reimbursement for medical procedures in which the products we currently, or intend to, commercialize are used, or that reduce medical procedure volumes, could adversely affect our operations and/or future business plans. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for medical devices affected by the legislation. From time to time, legislation is drafted, introduced, and passed that could significantly change the statutory provisions governing coverage, reimbursement, pricing, and marketing of medical device products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

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

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 since then. In addition, U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. A continuation or worsening of the levels of market disruption and volatility 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 March 2, 2022, the Company received notice from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between January 14, 2022, through March 1, 2022, we 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 until August 29, 2022 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

On August 30, 2022, the Company received notice from Nasdaq indicating that the Company's securities would be subject to delisting due to the Company's continued non-compliance with the minimum bid price requirement unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel, which stayed any further action by Nasdaq at least pending the issuance of a decision by the Panel and the expiration of any extension the Panel may grant to the Company following the hearing. On October 17, 2022, the Panel granted the Company's request for continued listing on The Nasdaq Capital Market until December 15, 2022, subject to the Company providing a written update to the Panel on December 15, 2022.

On February 8, 2023, the Company effected a reverse stock split of its common stock at a ratio of 1 post-split share for every 20 pre-split shares. The Company's common stock continued to be traded on the Nasdaq Capital Market under the symbol NAOV and began trading on a split-adjusted basis at market open on February 9, 2023.

On February 28, 2023 The Company was notified by Nasdaq that it regained compliance with all Nasdaq listing requirements and the matter was closed. See "Item 3. Legal Proceedings – Nasdaq Deficiency and Hearings Panel Decision," for a full description of the Nasdaq hearing and the Company's actions to regain compliance.

There is no assurance that we will maintain 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.

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.

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. We concluded that our internal control over financial reporting and related disclosure controls and procedures were not effective as of December 31, 2022. Our management is in the process of implementing 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, once fully implemented, will be sufficient to remediate such material weaknesses in our internal control over financial reporting that existed as of December 31, 2022.

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 December 31, 2023 with an option to renew the lease for an additional 24 months. The space is approximately 284 square meters. We pay approximately $4,200 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 12. Commitments and Contingencies," which information is incorporated herein by reference, for a description of pending and recent litigation.

Protrade Proceeding

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 vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, although denied all Protrade's claims, nevertheless awarded Protrade about $1.5 million, on the grounds that the Company allegedly failed to fulfill an order for reusable hydrogel patches placed after the Agreement was terminated. The arbitrator based her decision on the basis of testimony of Protrade's president who asserted that a patient would use in excess of 33 reusable patches per each device, which the Company believes is a grossly inflated number.

On April 5, 2022, Protrade filed a Petition with the Supreme Court of New York Nassau County seeking to confirm the Award. On April 13, 2022, the Company submitted an application to the ICA seeking to correct an error in the award based on the evidence that the Company only sold 2-3 reusable patches per device contrary to the 33 reusable patches claimed by Protrade. The same arbitrator who issued the award, denied the application.

On July 22, 2022, the Company filed a cross-motion seeking to vacate arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the Award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newel information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the Court denied the motion to re-argue and renew. The Company intends to file a notice of appeal with the Appellate Division, Second Department and to continue to vigorously pursue its opposition to the award in all appropriate fora.

As of December 31, 2022, the Company accrued the amount of the award to Protrade amounting to $1,500,250 as part of "General and administrative expenses". In addition, as the Company has not made payments on this award since it continues to appeal, the Company accrued the amount of $346,544 as part of "Interest Expense", with the total amount of $1,846,794 included in "Other accounts payable and accrued expenses".

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 17, 2023, we had 1,662,377 issued and outstanding shares of common stock. The common stock was held by 96 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.

On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders that was held on March 31, 2021, and ultimately adjourned until May 6, 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 May 6, 2021, the Company's stockholders voted to approve the ratification of 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 to be effective as of December 4, 2020, but the stockholders did not approve a further increase in the number of its authorized shares of common stock.

On August 17, 2021, the Company's stockholders voted to approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of shares of our common stock authorized for issuance from 24,109,635 shares to 40,000,000 shares.

As of April 17, 2023, we had a total of no 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 17, 2023, we had a total of no 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 17, 2023, we had a total of no 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.

As of April 17, 2023, we held no shares of our Series F Preferred Stock issued and outstanding. Each share of Series F Preferred Stock entitles the holder thereof to 1,000,000 votes per share (and, for the avoidance of doubt, each fraction of a share of Series F Preferred Stock has a ratable number of votes). Thus, each one-thousandth of a share of Series F Preferred Stock entitles the holder thereof to 1,000 votes. The outstanding shares of Series F Preferred Stock will vote together with the outstanding shares of common stock of the Company as a single class exclusively with respect to (1) any proposal to adopt an amendment to Certificate of Incorporation to reclassify the outstanding shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split") and (2) any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split (the "Adjournment Proposal"). The Series F Preferred Stock is not entitled to vote on any other matter, except to the extent required under the Delaware General Corporation Law.

Unless otherwise provided on any applicable proxy or ballot with respect to the voting on the Reverse Stock Split or the Adjournment Proposal, the vote of each share of Series F Preferred Stock (or fraction thereof) entitled to vote on the Reverse Stock Split, the Adjournment Proposal or any other matter brought before any meeting of stockholders held to vote on the Reverse Stock Split and the Adjournment Proposal will be cast in the same manner as the vote, if any, of the share of common stock (or fraction thereof) in respect of which such share of Series F Preferred Stock (or fraction thereof) was issued as a dividend is cast on the Reverse Stock Split, the Adjournment Proposal or such other matter, as applicable, and the proxy or ballot with respect to shares of common stock held by any holder on whose behalf such proxy or ballot is submitted will be deemed to include all shares of Series F Preferred Stock (or fraction thereof) held by such holder. Holders of Series F Preferred Stock will not receive a separate ballot or proxy to cast votes with respect to the Series F Preferred Stock on the Reverse Stock Split, the Adjournment Proposal or any other matter brought before any meeting of stockholders held to vote on the Reverse Stock Split. All shares of Series F Preferred Stock that are not present in person or by proxy at any meeting of stockholders held to vote on the Reverse Stock Split and the Adjournment Proposal as of immediately prior to the opening of the polls at such meeting (the "Initial Redemption Time") will automatically be redeemed in whole, but not in part, by the Company at the Initial Redemption Time without further action on the part of the Company or the holder of shares of Series F Preferred Stock (the "Initial Redemption"). Any outstanding shares of Series F Preferred Stock that have not been redeemed pursuant to an Initial Redemption will be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board in its sole discretion, automatically and effective on such time and date specified by the Board in its sole discretion or (ii) automatically upon the approval by the Company's stockholders of the Reverse Stock Split at any meeting of the stockholders held for the purpose of voting on such proposal (the "Subsequent Redemption" and, together with the Initial Redemption, the "Redemption"). As of December 31, 2022, both the Initial Redemption and the Subsequent Redemption have occurred. As a result, no shares of Series F Preferred Stock remain outstanding.

Each share of Series F Preferred Stock redeemed in any redemption described above will be redeemed in consideration for the right to receive an amount equal to $0.10 in cash for each one hundred whole shares of Series F Preferred Stock that are "beneficially owned" by the "beneficial owner" (as such terms are defined in the Certificate of Designation) thereof as of the applicable redemption time and redeemed pursuant to such redemption, payable upon receipt by the Company of a written request submitted by the applicable holder to the corporate secretary of the Company (each a "Redemption Payment Request") following the applicable redemption time. Such Redemption Payment Request shall (i) be in a form reasonably acceptable to the Company (ii) set forth in reasonable detail the number of shares of Series F Preferred Stock beneficially owned by the holder at the applicable redemption time and include evidence reasonably satisfactory to the Company regarding the same, and (iii) set forth a calculation specifying the amount in cash owed to such Holder by the Company with respect to the shares of Series F Preferred Stock that were redeemed at the applicable redemption time. However, the redemption consideration in respect of the shares of Series F Preferred Stock (or fractions thereof) redeemed in any redemption described above: (i) will entitle the former beneficial owners of less than one hundred whole shares of Series F Preferred Stock redeemed in any redemption to no cash payment in respect thereof and (y) will, in the case of a former beneficial owner of a number of shares of Series F Preferred Stock (or fractions thereof) redeemed pursuant to any redemption that is not equal to a whole number that is a multiple of one hundred, entitle such beneficial owner to the same cash payment, if any, in respect of such redemption as would have been payable in such redemption to such beneficial owner if the number of shares (or fractions thereof) beneficially owned by such beneficial owner and redeemed pursuant to such redemption were rounded down to the nearest whole number that is a multiple of one hundred (such, that for example, the former beneficial owner of 150 shares of Series F Preferred Stock redeemed pursuant to any redemption will be entitled to receive the same cash payment in respect of such redemption as would have been payable to the former beneficial owner of 100 shares of Series F Preferred Stock redeemed pursuant to such redemption).

Recent Sales of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2022 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. RESERVED

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

Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide a reader of our financial statements with a narrative from the perspective of our management on our financial condition, results of operations, liquidity, and certain other factors that may affect our future results. 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

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. During the first six months of 2020, the financial downturn compelled us to furlough or reduce working hours for much of our operating staff, and 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. Although there were no material disruptions during 2021, the COVID-19 pandemic 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.

Protrade Proceeding

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 vigorously defended the claims asserted by Protrade.

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On November 9, 2022, the Company filed a motion to re-argue and re-plead the arbitration decision based on additional information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. The Company expects to continue to vigorously pursue its opposition to the award in all appropriate fora.

As of December 31, 2022 and 2021, the Company accrued the amount of the award to Protrade amounting to approximately $1.9 million and $1.5 million, respectively, with the $0.4 million of interest accrued in 2022 as part of "Interest expense" and "Other accounts payable and accrued expenses".

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 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 our WoundShield product and technology. In addition, Sanuwave will bear the costs and clinical validation responsibilities associated with obtaining approval for WoundShield from the FDA and other regulatory agencies around the world.

In September 2020, the 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 Deficiency and Hearings Panel Decision

On March 2, 2022, the Company received a letter from Nasdaq indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between January 14, 2022, through March 1, 2022, 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 August 29, 2022 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

On August 30, 2022, the Company received notice from Nasdaq indicating that the Company's securities would be subject to delisting due to the Company's continued non-compliance with the minimum bid price requirement unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel, which stayed any further action by Nasdaq at least pending the issuance of a decision by the Panel and the expiration of any extension the Panel may grant to the Company following the hearing. On October 17, 2022, the Panel granted the Company's request for continued listing on The Nasdaq Capital Market until December 15, 2022, subject to the Company providing a written update to the Panel on December 15, 2022.

On September 13, 2022, subject to stockholder approval, the Board approved an amendment to our Certificate of Incorporation to, at the discretion of the Board, effect the reverse stock split of our common stock at a ratio of 1-for-2 to 1-for-50, with the exact ratio within such range to be determined by the Board at its discretion. The primary goal of the reverse stock split is to increase the per share market price of the Company's common stock to meet the minimum per share bid price requirements for continued listing on Nasdaq. As indicated by the Company's proxy statement filed on October 31, 2022, stockholders of the Company's common stock and Series F Preferred Stock were able to vote on the reverse stock split at the annual meeting held on December 15, 2022.

At an annual meeting of stockholders held on December 15, 2022, the Company's stockholders granted Board the discretion to effect a reverse stock split of the Company's common stock through an amendment to its Certificate of Incorporation at a ratio of not less than 1-for-2 and not more than 1-for-50, such ratio to be determined by the Board.

On February 8, 2023, the Company effected a reverse stock split of its common stock at a ratio of 1 post-split share for every 20 pre-split shares. The Company's common stock continued to be traded on the Nasdaq Capital Market under the symbol NAOV and began trading on a split-adjusted basis at market open on February 9, 2023.

On February 28, 2023 the Company was notified by Nasdaq that it regained compliance with all Nasdaq listing requirements and the matter was closed.

Regulatory Update

On May 26, 2022, we were notified by the U.S. Food and Drug Administration (the "FDA") that we should discontinue any new marketing of our PainShield Plus products until we receive the requisite regulatory clearance. The Company retained a qualified third-party laboratory to prepare and submit the appropriate 510(k) premarket notification to FDA. And, on November 28, 2023, the Company announced that the FDA officially granted 510(k) clearance of PainShield ® MD PLUS to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions, such as relief of pain, muscle spasms, and joint contractures.

In addition, the Company is working with the laboratory on our PainShield Relief product so that it meets the predicate product category specifications, There is no guarantee that we will ever be successful in obtaining FDA clearance or approval for the Painshield Relief products.

We also filed an application with the Centers for Medicare and Medicaid Services for reimbursement earlier this year. The application was rejected due to a lack of data supporting PainShield MD's life expectancy. We subsequently entered into an agreement with a qualified third-party laboratory to conduct testing that we hope will provide the necessary independent data to support our resubmission of an application for reimbursement.

Critical Accounting Policies and Significant Estimates

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reported period. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates if conditions differ from our assumptions. While our significant accounting policies are more fully described in Note 3 in the "Notes to Financial Statements", we believe the following accounting policies are critical to the process of making significant estimates in preparation of our financial statements.

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, 2022 and 2021, there was no allowance on inventory.

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.

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 create(s) 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.

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Stock-based compensation

We rely on the Black-Scholes option pricing model for estimating the fair value of stock-based awards granted, and expected volatility is based on the historical volatilities of peer company's common stock. Stock options generally vest over one or two years from the grant date and generally have ten-year contractual terms. Information about the assumptions used in the calculation of stock-based compensation expense is set forth in Notes 3 and 6 in the "Notes to Financial Statements".

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.

We recognize 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.

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

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Revenues. For the years ended December 31, 2022 and 2021, our revenues were approximately $752,000 and $1,695,000, respectively, a decrease of approximately 56%, or $943,000, between the periods. The decrease was attributable to absence of sales from our Ultra Pain Products distributor in the third and fourth quarter of 2022 due to suspension of PainShield Plus by the FDA. 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 years ended December 31, 2022, the percentage of revenues attributable to our products was: PainShield – 96% and UroShield – 4%. For the year ended December 31, 2021, the percentage of revenues attributable to our products was: PainShield – 99% and UroShield – 1%. For the years ended December 31, 2022 and 2021, the portion of our revenues that was derived from distributors was 89% and 93%, respectively.

Gross Profit. For the years ended December 31, 2022 and 2021, gross profit was approximately $167,000 and $770,000, respectively. The decrease was mainly due to the large decrease in revenues as we suspended sales of our most popular product, Painshield Plus, until we received marketing clearance from the FDA, which was not received until very late in the fourth quarter in 2022, and to a lesser degree due to (i) incurring additional labor and material costs due to in the third and fourth quarter of 2022 which usually produced higher margins in the prior years, production delays caused by the suspension of Painshield Plus by the FDA and minor changes we made to the product and its packaging to regain compliance, (ii) increases in certain components of our devices due to inflation, (iii) increased importing and delivery costs because of inflation and transportation supply chain issues and (iv) to a lesser degree obsolescence costs pertaining to certain components that were changed to regain compliance with the FDA as well as the retirement of inventory repurchased from a former customer pursuant to an agreement to cancel a contract that had certain exclusive international distribution rights.

Gross profit as a percentage of revenues were approximately 22% and 45% for the years ended December 31, 2022 and 2021, respectively. The decrease in gross profit as a percentage is mainly due to the reasons described above.

Research and Development Expenses. For the years ended December 31, 2022 and 2021, research and development expenses were approximately $283,000 and $293,000, respectively, a decrease of approximately 3%, or $10,000 between the periods. This decrease was mainly due to studies performed in the prior year and development of an over-the-counter PainShield product and a CBD application for our PainShield product in 2021 that did not occur in 2022.

Research and development expenses as a percentage of total revenues were approximately 38% and 17% for the years ended December 31, 2022 and 2021, respectively.

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 years ended December 31, 2022 and 2021, selling and marketing expenses were approximately $965,000 and $1,101,000, respectively, a decrease of approximately 12%, or $136,000 between the periods. The decrease in selling and marketing expenses was mainly due to 50% re-allocation of a sales executive's payroll to administrative costs amounting to $120,000 as his roles and responsibilities changed in 2022.

Selling and marketing expenses as a percentage of total revenues were approximately 128% and 65% for the years ended December 31, 2022 and 2021, respectively. The increase in our percentage was due to the decrease in revenues.

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

General and Administrative Expenses. For the years ended December 31, 2022 and 2021, general and administrative expenses were approximately $3,931,000 and $5,059,000, respectively, a decrease of approximately 22%, or $1,128,000 between the periods. The decrease was mainly due to the recognition of a $1,500,000 arbitration settlement expense in 2021 from final award of arbitration issued in favor of the Company's former distributor to cover for "lost profits" and reimbursement of arbitration costs.

Interest expense. For the years ended December 31, 2022 and 2021, were $347,000 and $0, respectively. This pertain to the interest on the Company's judgment liability in the current year.

Change in fair value of derivative liabilities. For the years ended December 31, 2022 and 2021, there was a change in fair value of derivative liabilities resulting in a loss of approximately $0 and $6,956,000, respectively. The loss in 2021 was derived from the Company's total potentially dilutive shares exceed the Company's authorized share limit.

Gain on purchase of warrants. For the years ended December 31, 2022 and 2021, there was a gain of approximately $0 and $64,000, respectively. The gain in 2021 was related to the settlement of derivative liabilities which was the result of the repurchase of warrants from certain investors.

Warrant modification expense. For the years ended December 31, 2022 and 2021, warrant modification expense was approximately $0 and $1,627,000, respectively. The warrant modification expense was due to the resolution of the over-issuance shares matter. The over-issuance shares matter resulted in a reclassification of derivative liabilities to equity during 2021. There was no warrant modification in 2022.

Income tax expense. For the years ended December 31, 2022 and 2021, our income tax expense was approximately $35,000 and $32,000, respectively. The low tax expense for 2021 was a result of favorable adjustments due to lapses of statutes of limitations on its Israel tax positions. In 2022, there was no such adjustment.

Net Loss. Our net loss decreased by approximately $8,834,000 or 62%, to approximately $5,448,000 for the years ended December 31, 2022 from approximately $14,282,000 during the same period in 2021. 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 $5,448,000 during the year ended December 31, 2022, which primarily consisted of decreased revenues and increase in interest expense from judgement liability. We also had negative cash flow from operating activities of $7,035,000 for the year ended December 31, 2022. Although we received proceeds from sale of common stock amounting to $2,090,000 and had a cash balance of just over $2,713,000 as of December 31, 2022, we expect to continue to incur losses and negative cash flows from operating activities, and therefore, we do not have sufficient resources to fund our operation for the next twelve months from the date of this filing causing us to have substantial doubt of the Company's ability to continue as a going concern The Company will need to continue to raise additional capital to finance its losses and negative cash flows from operations beyond the next years 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, 2022, we met our short-term liquidity requirements from our existing cash reserves and proceeds from sale of common stock. 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. There are no assurances that we are able to raise additional capital, as required, on terms favorable to us.

We do not have any material commitments to capital expenditures as of December 31, 2022, and we are not aware of any material trends in capital resources that would impact our business.

As of December 31, 2022, we have no off-balance sheet transactions, arrangements, obligations (including contingent 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.

Years Ended December 31, 2022 Compared to Years Ended December 31, 2021

General. As of December 31, 2022, we had cash of approximately $2,713,000, compared to approximately $7,737,000 as of December 31, 2021. 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 $7,035,000 for the years ended December 31, 2022 and approximately $4,367,000 for the same period in 2021. The increase in our net cash used in operating activities in the amount of $2,668,000 is mainly attributable to the increase in changes in working capital accounts, partially offset by decrease in noncash expense of arbitration settlement expense and warrant modification expense.

Cash used in our investing activities was approximately $3,000 for both years ended December 31, 2022 and 2021 from purchases of fixed assets.

Cash provided by financing activities during the year ended December 31, 2022 was approximately $2,092,000, which was composed of the net proceeds received from the sale of common stock and exercise of employee stock options in 2022 compared to $4,580,000 in 2021, which was the net proceeds received from the exercise of warrants completed in 2021. 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.

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.

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, 2022, the Company's disclosure controls and procedures are not effective due to the material weaknesses described below. In light of this fact, our management has performed additional analyses, reconciliations, and other post-closing procedures and has concluded that, notwithstanding the material weaknesses in our internal control over financial reporting, the consolidated financial statements for the periods covered by and included in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

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, 2022 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, 2022, as the result of the material weaknesses 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. In previously filed Annual Reports on Form 10-K's, we disclosed material weaknesses related to the design and effectiveness of our internal control over financial reporting.

- 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, (3) proper accounting of 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, and (4) lacking 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.

- Additionally, we did not maintain effective controls over the operating effectiveness of information technology ("IT") general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not establish or formalize appropriate IT policies, segregation of duties and monitoring procedures and without monitoring procedures over third-party service providers, did not evaluate whether the providers were appropriately managing its and the Company's IT infrastructure, operations, and critical financial systems.

- As of December 31, 2022, we did not have adequate controls in place to ensure adequate review, including (1) effective controls over our IT 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 implemented a new inventory system in the fourth quarter of 2021 which lacked adequate inventory control procedures, (4) 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, and (5) we did not maintain effective controls over the operating effectiveness of IT general controls for information systems that are relevant to the preparation of their financial statements.

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

To date, we have implemented certain measures to address the identified material weaknesses. These measures include adding personnel as well as improving our internal controls around financial systems and processes. We intend to continue to take steps to remediate the material weaknesses described above and further evolve our internal controls and processes. We will not be able to remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time. The following remedial actions were taken through the year ended December 31, 2021:

- We have been able to remediate the material weakness identified above with respect to the issuance of shares in excess of the number of authorized shares in 2021 and implemented a plan in place to have adequate controls in place to avoid future issuances in excess of authorized shares. The Company took steps to remediate the stock issuance material weakness through creating procedures over the approval of any new equity issuances to ensure that there are no further over-issuances which includes the creation of an equity roll forward master sheet that must be approved and signed off by senior management before the issuance of any new equity issuances, including warrants, stock options and issuances of any shares of stock.

The following remedial actions were taken during the year ended December 31, 2022:

- With assistance from a current finance and accounting third-party service provider, the Company is formalizing our risk assessment process, policies and procedures, implementing revised control activities, controls documentation, and ongoing monitoring activities related to the internal controls over financial reporting including testing documentation to provide evidence that our system of internal controls over financial reporting meets the requirements of the COSO 2013 framework, and provide a foundation for the Company to communicate internal control deficiencies in a timely manner to those parties responsible for taking corrective action.
- expanded consultations with third party specialists on complex accounting matters, financial reporting and regulatory filings,
- enhanced documentation to support a more precise review process,
- enhanced monitoring of the review process, and
- review of inventory recording system.

During the period covered by this Annual Report on Form 10-K, with exception for the issuance of excess shares, 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, 2022. 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.

In addition, under the direction of the audit committee of the Board of Directors, management will continue to review and make necessary changes to the overall design of the Company's internal control environment, as well as to refine policies and procedures to improve the overall effectiveness of internal control over financial reporting of the Company.

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, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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 2023 annual meeting of stockholders, which shall be filed with the Securities and Exchange Commission no later than May 1, 2023 (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, 2022 and 2021, 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, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

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

/s/ Marcum LLP

Marcum LLP

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

New York, NY
April 17, 2023

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

	December 31, 2022	December 31, 2021
ASSETS:		
Current assets:		
Cash	$ 2,713	$ 7,737
Trade receivables	9	200
Prepaid expenses and other accounts receivable	712	230
Inventory	2,175	175
Total current assets	5,609	8,342
Noncurrent assets:		
Fixed assets, net	7	5
Other assets	3	19
Severance pay fund	179	207
Operating lease right-of-use assets, net	81	49
Total non-current assets	270	280
Total assets	$ 5,879	$ 8,622
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Trade payables	$ 66	$ 87
Other accounts payable and accrued expenses	2,148	1,723
Deferred revenue	21	44
Operating lease liabilities, current	81	49
Total current liabilities	2,316	1,903
Non-current liabilities:		
Accrued severance pay	223	253
Deferred licensing income	107	153
Total liabilities	2,646	2,309
Commitments and contingencies		
Stockholders' equity:		
Series C Preferred stock of $0.001 par value - Authorized: 3,000,000 shares at both December 31, 2022 and 2021; Issued and outstanding: 0 shares at both December 31, 2022 and 2021, respectively	-	-
Series D Preferred stock of $0.001 par value - Authorized: 506 shares at both December 31, 2022 and 2021; Issued and outstanding: 0 shares at both December 31, 2022 and 2021, respectively	-	-
Series E Preferred stock of $0.001 par value - Authorized: 1,999,494 shares at both December 31, 2022 and 2021, respectively; Issued and outstanding: 0 shares at both December 31, 2022 and 2021, respectively	-	-
Series F Preferred stock of $0.01 par value - Authorized: 40,000 and 0 shares at December 31, 2022 and 2021, respectively; Issued and outstanding: 0 shares at both December 31, 2022 and 2021, respectively	-	-
Common stock of $0.001 par value - Authorized: 40,000,000 shares at December 31, 2022 and December 31, 2021, respectively; Issued and outstanding: 1,641,146 and 1,399,890 shares at December 31, 2022 and December 31, 2021, respectively	2	1
Additional paid in capital	65,634	63,189
Accumulated other comprehensive income	(18)	60
Accumulated deficit	(62,385)	(56,937)
Total stockholders' equity	3,233	6,313
Total liabilities and stockholders' equity	$ 5,879	$ 8,622

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

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

	Year Ended December 31,	
	2022	**2021**
Revenues	$ 752	$ 1,695
Cost of revenues	585	925
Gross profit	167	770
Operating expenses:		
Research and development	283	293
Selling and marketing	965	1,101
General and administrative	3,931	5,059
Total operating expenses	5,179	6,453
Loss from operations	(5,012)	(5,683)
Interest expense	(347)	-
Financial expense, net	(54)	(48)
Change in fair value of derivative liabilities	-	(6,956)
Gain on purchase of warrants	-	64
Warrant modification expense	-	(1,627)
Loss before taxes	(5,413)	(14,250)
Income tax expense	(35)	(32)
Net loss	$ (5,448)	$ (14,282)
Basic and diluted net loss available for holders of common stock, Series C Preferred Stock and Series D Preferred Stock	$ (3.84)	$ (11.35)
Weighted average common shares outstanding:		
Basic and diluted	1,419,670	1,258,141
Comprehensive loss:		
Net loss available to common stockholders	(5,448)	(14,282)
Change in foreign currency translation adjustments	(78)	(6)
Comprehensive loss available to common stockholders	(5,526)	(14,288)

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

NanoVibronix, Inc.
Consolidated Statement of Stockholders' Equity

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Series F 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	Shares	Amount				
Balance, December 31, 2020	666,667	$ 1	153	$ -	875,000	$ 1	-	$ -	1,062,326	$ 1	$ 44,980	$ 66	$ (42,655)	$ 2,394
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	190	-	-	190
Exercise of warrants	-	-	-	-	-	-	-	-	252,830	-	7,056	-	-	7,056
Reclass of derivative liabilities to APIC	-	-	-	-	-	-	-	-	-	-	10,963	-	-	10,963
Conversion of Series C Preferred Stock into Common Stock	(666,667)	(1)	-	-	-	-	-	-	33,333	-	-	-	-	(1)
Conversion of Series D Preferred Stock into Common Stock	-	-	(153)	-	-	-	-	-	7,650	-	-	-	-	-
Conversion of Series E Preferred Stock into Common Stock	-	-	-	-	(875,000)	(1)	-	-	43,750	-	-	-	-	(1)
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(6)	-	(6)
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(14,282)	(14,282)
Balance, December 31, 2021	-	$ -	-	$ -	-	$ -	-	$ -	1,399,890	$ 1	$ 63,189	$ 60	$ (56,937)	$ 6,313
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	354	-	-	354
Issuance of common stock, net of offering costs of $310,424	-	-	-	-	-	-	-	-	240,000	1	2,089	-	-	2,090
Issuance of redeemable Series F preferred stock	-	-	-	-	-	-	27,998	-	-	-	-	-	-	-
Redemption of redeemable Series F preferred stock	-	-	-	-	-	-	(27,998)	-	-	-	-	-	-	-
Exercise of options	-	-	-	-	-	-	-	-	1,256	-	2	-	-	2
Other comprehensive loss	-	-	-	-	-	-	-	-	-	-	-	(78)	-	(78)
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(5,448)	(5,448)
Balance, December 31, 2022	-	$ -	-	$ -	-	$ -	-	$ -	1,641,146	$ 2	$ 65,634	$ (18)	$ (62,385)	$ 3,233

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

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

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (5,448)	$ (14,282)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	2
Stock-based compensation	354	382
Noncash interest expense	347	-
Arbitration settlement expense	-	1,500
Warrant modification expense	-	1,627
Change in fair value of equity investment	16	6
Change in fair value of derivative liabilities	-	6,956
Gain on purchase of warrants	-	(64)
Changes in operating assets and liabilities:		
Trade receivable	191	(175)
Other accounts receivable and prepaid expenses	(482)	37
Inventory	(2,000)	(30)
Trade payables	(21)	(59)
Other accounts payable and accrued expenses	78	(265)
Deferred revenue	(69)	(2)
Accrued severance pay, net	(2)	-
Net cash used in operating activities	(7,035)	(4,367)
Cash flows from investing activities:		
Purchases of fixed assets	(3)	(3)
Net cash used in investing activities	(3)	(3)
Cash flows from financing activities:		
Proceeds from sale of common stock, net	2,090	-
Proceeds from exercise of options	2	-
Proceeds from exercise of warrants	-	4,968
Buy back of warrants from investor	-	(388)
Net cash provided by financing activities	2,092	4,580
Effects of currency translation on cash	(78)	(6)
Net (decrease) increase in cash	(5,024)	204
Cash at beginning of period	7,737	7,533
Cash at end of period	$ 2,713	$ 7,737
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -
Supplemental non-cash financing and investing activities:		
Exchange of common stock into preferred stock	$ -	$ 1
Shares issued from exercise of warrants previously classified as derivative liability	$ -	$ 2,087
Reclass derivative liability to equity due to increase in authorized shares	$ -	$ 8,706
Reclass liability to equity after increase in authorized 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. In 2022, the Company's cash used in operations was $7,035 and received net proceeds of $2,090 (net of offering costs of $310,424) from the sale of our equity securities, leaving a cash balance of $2,713 as of December 31, 2022. Because the Company does not have sufficient resources to fund our operation for the next twelve months from the date of this filing, management has substantial doubt of the Company's ability to continue as a going concern. The Company will need to raise additional capital to finance its losses and negative cash flows from operations and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability.

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 consolidated financial statements and accompanying notes have been prepared in conformity with U.S. generally accepted accounting principles ("US GAAP").

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 losses and gains as of the years ended December 31, 2022 and 2021 were $85 and $6, 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, 2022 and 2021, 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, 2022 and 2021, 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.

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, 2022 and 2021 was $223 and $253, respectively.

Leases

The Company accounts for its leases in accordance with ASU 2016-02, "Leases" (Topic 842). This topic requires that a lessee recognize the assets and liabilities that arise from operating leases. The Company recognizes right-of-use assets and lease liabilities on the consolidated balance sheet for all leases with a term longer than 12 months and classify them as operating leases. For leases with a term of 12 months or less, the Company elects to implement in a class of underlying asset not to recognize lease assets and lease liabilities. The right-of-use assets and lease liabilities have been measured by the present value of the Company's remaining lease payments over the lease term using our incremental borrowing rates or implicit rates, when readily determinable.

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 create(s) 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 compensation

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 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. This ASU is effective for interim and annual reporting periods beginning after December 15, 2022. The adoption of Topic 326 did not have a material effect on the Company's consolidated financial statements.

NOTE 4 - PREPAID EXPENSES AND OTHER RECEIVABLES

Prepaid expenses and other receivables consist of the following:

	December 31,	
	2022	**2021**
Prepaid expenses	$ 612	$ 166
Other receivables	100	64
	$ 712	$ 230

NOTE 5 – INVENTORY

Inventory consists of the following components:

	December 31,	
	2022	2021
Raw materials	$ 30	$ -
Finished goods	2,145	175
	$ 2,175	$ 175

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.

On August 17, 2021, the Company's stockholders voted to approve an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of shares of the Company's Common Stock authorized for issuance from 24,109,635 shares to 40,000,000 shares. As a result of the vote to increase the number of shares authorized for issuance, the warrants that were previously accounted for as derivative liabilities were marked to market through the date of approval and then reclassified to additional paid in capital (equity), as the Company had sufficient authorized shares to settle the exercise of the warrants.

Issuance of common stock for cash

On November 29, 2022, the Company entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company agreed to sell in a registered direct offering (the "Offering"), 240,000 shares of the Company's common stock at an offering price of $10.00 per share. The Company received net proceeds from the sale of such offering, after deducting placement agent fees and expenses and offering expenses payable by the Company, of approximately $2.1 million. The Company intends to use the net proceeds for general working capital purposes.

On October 6, 2022, the Company entered into an engagement letter with H.C. Wainwright & Co., LLC (the "Wainwright"), pursuant to which Wainwright agreed to serve as the exclusive placement agent for the Company, on a reasonable best-efforts basis, in connection with the Offering. The Company will pay Wainwright an aggregate cash fee equal to 7.5% of the gross proceeds of the Offering, a management fee equal to 1.0% of the gross proceeds of the Offering, a non-accountable expense allowance of $50,000 and $15,950 for clearing fees. Additionally, the Company has agreed to issue to Wainwright or its designees as compensation, warrants to purchase up to 18,000 shares of common stock. The warrants expire on November 29, 2027 and have an exercise price of $12.50 per share.

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 twentieth of a 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 years ended December 31, 2022 and 2021, shareholders converted 0 and 875,000 shares of Series E Preferred Stock into 0 and 43,750 shares of common stock, respectively, at a conversion rate of 20 to 1. No purchase was made to convert these shares.

Each share of Series D Preferred Stock is convertible into fifty 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 years ended December 31, 2022 and 2021, shareholders converted 0 and 153 shares of Series D Preferred Stock into 0 and 7,650 shares of common stock, respectively, at a conversion rate of 1 to 50. No purchase was made in order to convert these shares.

Each share of Series C Preferred Stock is convertible into one twentieth of a 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 years ended December 31, 2022 and 2021, shareholders converted 0 and 666,667 shares of Series C Preferred Stock into 0 and 33,333 shares of common stock, respectively, at a conversion rate of 20 to 1. No purchase was made in order to convert these shares.

Series F Preferred Stock

On September 13, 2022, the Board declared a dividend of one one-thousandth of a share of Series F Preferred Stock, par value $0.001 per share ("Series F Preferred Stock"), for each one share of the Company's common stock, par value $0.001 per share, to stockholders of record at 5:00 p.m. Eastern Time on October 14, 2022.

Each share of Series F Preferred Stock entitles the holder thereof to 1,000,000 votes per share (and, for the avoidance of doubt, each fraction of a share of Series F Preferred Stock has a ratable number of votes). Thus, each one-thousandth of a share of Series F Preferred Stock entitles the holder thereof to 1,000 votes. The outstanding shares of Series F Preferred Stock will vote together with the outstanding shares of common stock of the Company as a single class exclusively with respect to (1) any proposal to adopt an amendment to Certificate of Incorporation to reclassify the outstanding shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split") and (2) any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split (the "Adjournment Proposal"). The Series F Preferred Stock is not entitled to vote on any other matter, except to the extent required under the Delaware General Corporation Law.

Unless otherwise provided on any applicable proxy or ballot with respect to the voting on the Reverse Stock Split or the Adjournment Proposal, the vote of each share of Series F Preferred Stock (or fraction thereof) entitled to vote on the Reverse Stock Split, the Adjournment Proposal or any other matter brought before any meeting of stockholders held to vote on the Reverse Stock Split and the Adjournment Proposal will be cast in the same manner as the vote, if any, of the share of common stock (or fraction thereof) in respect of which such share of Series F Preferred Stock (or fraction thereof) was issued as a dividend is cast on the Reverse Stock Split, the Adjournment Proposal or such other matter, as applicable, and the proxy or ballot with respect to shares of common stock held by any holder on whose behalf such proxy or ballot is submitted will be deemed to include all shares of Series F Preferred Stock (or fraction thereof) held by such holder. Holders of Series F Preferred Stock will not receive a separate ballot or proxy to cast votes with respect to the Series F Preferred Stock on the Reverse Stock Split, the Adjournment Proposal or any other matter brought before any meeting of stockholders held to vote on the Reverse Stock Split. All shares of Series F Preferred Stock that are not present in person or by proxy at any meeting of stockholders held to vote on the Reverse Stock Split and the Adjournment Proposal as of immediately prior to the opening of the polls at such meeting (the "Initial Redemption Time") will automatically be redeemed in whole, but not in part, by the Company at the Initial Redemption Time without further action on the part of the Company or the holder of shares of Series F Preferred Stock (the "Initial Redemption"). Any outstanding shares of Series F Preferred Stock that have not been redeemed pursuant to an Initial Redemption will be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board in its sole discretion, automatically and effective on such time and date specified by the Board in its sole discretion or (ii) automatically upon the approval by the Company's stockholders of the Reverse Stock Split at any meeting of the stockholders held for the purpose of voting on such proposal (the "Subsequent Redemption" and, together with the Initial Redemption, the "Redemption"). As of December 31, 2022, both the Initial Redemption and the Subsequent Redemption have occurred. As a result, no shares of Series F Preferred Stock remain outstanding.

Each share of Series F Preferred Stock redeemed in any redemption described above will be redeemed in consideration for the right to receive an amount equal to $0.10 in cash for each one hundred whole shares of Series F Preferred Stock that are "beneficially owned" by the "beneficial owner" (as such terms are defined in the Certificate of Designation) thereof as of the applicable redemption time and redeemed pursuant to such redemption, payable upon receipt by the Company of a written request submitted by the applicable holder to the corporate secretary of the Company (each a "Redemption Payment Request") following the applicable redemption time. Such Redemption Payment Request shall (i) be in a form reasonably acceptable to the Company (ii) set forth in reasonable detail the number of shares of Series F Preferred Stock beneficially owned by the holder at the applicable redemption time and include evidence reasonably satisfactory to the Company regarding the same, and (iii) set forth a calculation specifying the amount in cash owed to such Holder by the Company with respect to the shares of Series F Preferred Stock that were redeemed at the applicable redemption time. However, the redemption consideration in respect of the shares of Series F Preferred Stock (or fractions thereof) redeemed in any redemption described above: (i) will entitle the former beneficial owners of less than one hundred whole shares of Series F Preferred Stock redeemed in any redemption to no cash payment in respect thereof and (y) will, in the case of a former beneficial owner of a number of shares of Series F Preferred Stock (or fractions thereof) redeemed pursuant to any redemption that is not equal to a whole number that is a multiple of one hundred, entitle such beneficial owner to the same cash payment, if any, in respect of such redemption as would have been payable in such redemption to such beneficial owner if the number of shares (or fractions thereof) beneficially owned by such beneficial owner and redeemed pursuant to such redemption were rounded down to the nearest whole number that is a multiple of one hundred (such, that for example, the former beneficial owner of 150 shares of Series F Preferred Stock redeemed pursuant to any redemption will be entitled to receive the same cash payment in respect of such redemption as would have been payable to the former beneficial owner of 100 shares of Series F Preferred Stock redeemed pursuant to such redemption).

No shares of Series F Preferred Stock may be transferred by the holder thereof except in connection with a transfer by such holder of any shares of common stock held by such holder, in which case a number of one one-thousandths (1/1,000ths) of a share of Series F Preferred Stock equal to the number of shares of common stock to be transferred by such holder will be automatically transferred to the transferee of such shares of common stock. The holders of Series F Preferred Stock, as such, are not entitled to receive dividends of any kind.

The Certificate of Designation was filed with the Delaware Secretary of State and became effective on September 14, 2022.

As described in the proxy statement filed on October 31, 2022, holders of The Company's common stock and Series F Preferred Stock as of the close of business on October 17, 2022, are entitled to vote on the amendment to the Company's Certificate of Incorporation to effect, at the discretion of the Company's Board but prior to the six-month anniversary of the date on which the reverse stock split is approved by the Company's stockholders at the Annual Meeting, a reverse stock split of all of the outstanding shares of the Company's common stock at a ratio in the range of 1-for-2 to 1-for-50, with such ratio to be determined by the Board in its discretion and included in a public announcement, and the proposal to adjourn the Annual Meeting to a later date at the Annual Meeting held on December 15, 2022.

Stock-based compensation and options

During the years ended December 31, 2022 and 2021, 1,256 and 0 employee options were exercised, and 21,875 and 43,875 options were granted, respectively. The options granted during 2022 and 2021 vest at different schedules ranging from date granted to 9 years and were recorded at fair values of $201 and $583, respectively. During the years ended December 31, 2022 and 2021, stock-based compensation expense of $148 and $258 was recorded for options that vested, respectively.

	Shares Under Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding – December 31, 2021	127,000	$ 31.86	7.77
Granted	21,875	10.76	9.55
Forfeited	-	-	-
Expired	-	-	-
Exercised	(1,256)	1.40	0.24
Outstanding – December 31, 2022	147,619	$ 24.42	7.24

The fair value for options granted in 2022 and 2021 is estimated at the date of grant using a Black-Scholes-Merton options pricing model with the following underlying assumptions:

	2022	2021
Price at valuation	$ 0.45 – 0.78	$ 0.72 – 2.07
Exercise price	$ 0.45 – 0.78	$ 0.72 – 2.07
Risk free interest	2.32 – 3.58%	0.27 – 1.29%
Expected term (in years)	5	5
Volatility	125.3 – 127.9%	60.9 – 82.7%

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,	
	2022	**2021**
Research and development	$ 6	$ 13
Selling and marketing	25	28
General and administrative	323	341
Total	$ 354	$ 382

As of December 31, 2022, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $328, which is expected to be recognized over a weighted average period of approximately 7.24 years.

Warrants

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) 295,714 shares of the Company's common stock at an offering price of $14.00 per share and (ii) pre-funded warrants to purchase up to 132,857 shares of common stock at a purchase price of $13.98 per pre-funded warrant, for gross proceeds of approximately $6.0 million, and net proceeds of approximately $5.4 million. In January 2021, two investors exercised an aggregate of 82,857 warrants at $0.02 per share.

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 60,298 shares of the Company's common stock at an exercise price per share of $23.30 (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 received new unregistered warrants to purchase up to an aggregate of 60,298 shares of common stock (the "New Warrants") at an exercise price of $20.80 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.

The New Warrants were 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 $1,627 was recorded with a corresponding increase in additional paid in capital.

In August and September 2021, investors exercised warrants to purchase 109,675 shares of common stock between $17.60 and $50.00 per share for proceeds of approximately $3.6 million.

On June 14, 2022, the Company issued warrants to two sales consultants to purchase 12,500 shares of common stock which will expire on June 14, 2029 and have an exercise price of $20.00 per share. Accordingly, expense related to these warrants in the amount of $135,000 was recorded with a corresponding increase in additional paid in capital.

On September 30, 2022, the Company and the two sales consultants mutually agreed to cancel the latter's annual stock warrants to purchase 12,500 shares of common stock. Accordingly, expense related to these warrants were reversed in the amount of $135,000 with a corresponding decrease in additional paid in capital.

On November 29, 2022, the Company granted 18,000 warrants to purchase Company's common stock in conjunction with the private placements.

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

	2022	2021
Risk free interest	0.34%	1.44%
Dividend yield	0%	0%
Volatility	60.7%	55.6 - 56.5 %
Contractual term (in years)	5	2

	Warrants
Outstanding – December 31, 2020	386,237
Granted	60,298
Exercised	(252,830)
Exercised - cashless	(14,071)
Expired	(31,000)
Canceled	(33,167)
Outstanding – December 31, 2021	115,467
Granted	30,500
Expired	(55,215)
Canceled	(12,500)
Outstanding – December 31, 2022	78,252

NOTE 7 - DERIVATIVE LIABILITIES

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.

On April 6, 2021, the Company agreed to buy back 33,167 warrants from investors for a total of $368. The warrants had exercise prices between $17.6 and $18.8 per share. The value of the derivative liabilities associated with these warrants was $451. The Company recorded a $64 gain in connection with the buyback of the warrants.

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 years ended December 31, 2022 and 2021 is as follows:

	2022	2021
Stock price	$ 1.01 – 2.94	$ 1.01 – 2.94
Conversion price	$ 0.72 – 6.90	$ 0.72 – 6.90
Contractual term (in years)	0.67 – 6.56	0.67 – 6.56
Volatility (annual)	82.70 – 211%	82.70 - 211%
Risk-free rate	0.09 – 1.21%	0.09 – 1.21%

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.

NOTE 8 – LEASES

The Company has operating lease agreements with terms up to 2-3 years, including car and office space leases.

The Company's weighted-average remaining lease term relating to its operating leases is 1.05 years, with a weighted-average discount rate of 10%.

The Company incurred $75 of lease expense for its operating leases for the year ended December 31, 2022.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of December 31, 2022:

2023	73
2024	4
Total undiscounted operating lease payments	77
Less: Imputed interest	4
Present value of operating lease liabilities	$ 73

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, 2022 and 2021 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, 2022	December 31, 2021
Stock options - employee and non-employee	147,619	127,000
Warrants	78,252	115,467
Total	225,871	242,467

The diluted loss per share equals basic loss per share in the year ended December 31, 2022 and 2021 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,	
	2022	2021
United States	$ 710	$ 1,627
Europe	25	18
Australia	9	6
India	3	-
Israel	-	5
Other	5	39
Total	$ 752	$ 1,695

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:

	2022	2021
Price at valuation	$ 0.02	$ 0.19 – 0.26
Exercise price	$ 0.19	$ 0.19
Risk free interest	3.96%	0.66 – 0.73 %
Expected term (in years)	8	10
Volatility	155.6%	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 years ended December 31, 2022 and 2021 was $3 and $19, respectively. There was a net $16 and $6 change in fair value during the year ended December 31, 2022 and 2021, respectively.

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, 2022 and 2021.

The following table presents changes in Level 3 asset and liability measured at fair value for the years ended December 31, 2022 and 2021:

	As of December 31, 2022	
	Asset	Liability
Balance – December 31, 2020	$ 25	$ 2,471
New Issuances	-	1,819
Fair value adjustments – Sanuwave warrants	(6)	-
Fair value adjustments – Warrant liability	-	6,956
Reclassification liability to equity	-	(10,793)
Buy back of warrants	-	(453)
Balance – December 31, 2021	$ 19	$ -
New Issuances	-	-
Fair value adjustments – Sanuwave warrants	(16)	-
Balance – December 31, 2022	$ 3	$ -

The following table sets forth the Company's assets and liabilities which are measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair Value Measurements as of December 31, 2022			
	Level I	Level II	Level III	Total
Asset:				
Other assets	$ -	$ -	$ 3	$ 3

	Fair Value Measurements as of December 31, 2021			
	Level I	Level II	Level III	Total
Asset:				
Other assets	$ -	$ -	$ 19	$ 19

NOTE 12 - COMMITMENTS AND CONTINGENCIES

Pending and settled 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.

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 vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, although denied all Protrade's claims, nevertheless awarded Protrade about $1.5 million, on the grounds that the Company allegedly failed to fulfill an order for reusable hydrogel patches placed after the Agreement was terminated. The arbitrator based her decision on the basis of testimony of Protrade's president who asserted that a patient would use in excess of 33 reusable patches per each device, which the Company believes is a grossly inflated number.

On April 5, 2022, Protrade filed a Petition with the Supreme Court of New York Nassau County seeking to confirm the Award. On April 13, 2022, the Company submitted an application to the ICA seeking to correct an error in the award based on the evidence that the Company only sold 2-3 reusable patches per device contrary to the 33 reusable patches claimed by Protrade. The same arbitrator who issued the award, denied the application.

On July 22, 2022, the Company filed a cross-motion seeking to vacate arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the Award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newel information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the Court denied the motion to re-argue and renew. The Company intends to file a notice of appeal with the Appellate Division, Second Department and to continue to vigorously pursue its opposition to the award in all appropriate fora.

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 TRANSACTION

The firm of FisherBroyles LLP is handling our Protrade litigation and appeals. For the year ended December 31, 2022, we have been billed and paid legal fees from Fisher Broyles amounting to $256,908 and recorded as part of "General and administrative expenses" in the condensed consolidated statements of operations. As has been previously disclosed, one of our board members, Aurora Cassirer, is a partner at Fisher Broyles. Ms. Cassirer does not provide any legal services or legal advice to the Company**.**

NOTE 14 – INCOME TAXES

As of December 31, 2022, the U.S. Company had federal and state net operating loss carry forward for tax purposes of approximately $33,000 and $6,000, respectively. $19,200 of the federal net operating loss can be carried forward indefinitely but can only offset up to 80% of taxable income in a given year, and $14,000 of the federal net operating loss can be used to fully offset taxable income in the period it is utilized but can only 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. The Company has not performed an analysis, but the potential impact of any limitation would not be material to the financial statements due to the fact that the respective DTAs are fully offset by a valuation allowance.

Income tax expense is comprised of the following:

	Year ended December 31,	
	2022	2021
Current Tax		
Federal	$ -	$ -
State	-	-
Foreign	37	32
Total	$ 37	$ 32
Deferred Tax		
Federal	$ (1,545)	$ (1,263)
State	653	(131)
Foreign	$ (1)	(4)
Total	$ (893)	$ (1,398)
Less: Valuation Allowance	893	1,398
Total Tax	$ 37	$ 32

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,	
	2022	2021
Federal income tax benefit at statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	-12.06%	0.92%
Foreign rate differential	-0.03%	0.02%
Permanent Items	-0.61%	-13.04%
Change in valuation allowance	-16.61%	-9.81%
Return to provision adjustments	7.54%	-0.01%
Forfeited options	0.00%	-0.16%
Other	0.09%	0.86%
Effective tax rate	-0.68%	-0.22%

Foreign tax

Tax rates applicable to the income of the Israeli subsidiary:

The Israeli corporate tax rate in 2022 and 2021 is 23%.

The subsidiary has final tax assessments through 2016.

Loss before taxes:

	Year ended December 31,	
	2022	2021
Domestic	$ 5,557	$ 14,333
Foreign	(144)	(82)
	$ 5,413	$ 14,250

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,	
	2022	2021
Deferred tax assets:		
Net operating loss carry forward	$ 7,306	$ 6,563
Arbitration accrual	414	414
Stock compensation and other	483	327
Deferred tax assets before valuation allowance	8,203	7,304
Valuation allowance	(8,203)	(7,304)
Net deferred tax asset	$ -	$ -

For the year ended December 31, 2022 and 2021, the net increases in valuation allowance of $894 and $1,417, 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, 2022 and 2021.

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's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of December 31, 2022 and 2021, the Company does not have any liabilities recorded for uncertain tax positions and does not expect there to be any events which could potentially result in the need for a material liability to be recorded. There were no changes in the Company's unrecognized tax benefits during the years ended December 31, 2022 and 2021. The Company did not recognize any interest or penalties during fiscal 2022 or 2021 related to unrecognized tax benefits.

U.S. federal and New York State income taxes are open for examination for years 2019-2022 and Israel tax returns are open for examination for years 2018-2022.

NOTE 15 - SUBSEQUENT EVENTS

On February 8, 2023, the Company effected a reverse stock split of its common stock at a ratio of 1 post-split share for every 20 pre-split shares. The Company's common stock begin trading on a split-adjusted basis when the market opened on February 9, 2023.

At an annual meeting of stockholders held on December 15, 2022, the Company's stockholders granted the Company's Board of Directors the discretion to effect a reverse stock split of the Company's common stock through an amendment to its Amended and Restated Certificate of Incorporation at a ratio of not less than 1-for-2 and not more than 1-for-50, with such ratio to be determined by the Company's Board of Directors.

At the effective time of the reverse stock split, every 20 shares of the Company's issued and outstanding common stock was converted automatically into one issued and outstanding share of common stock without any change in the par value per share. Stockholders holding shares through a brokerage account had their shares automatically adjusted to reflect the 1-for-20 reverse stock split. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the reverse stock split resulted in a stockholder owning a fractional share. Any fractional share of a stockholder resulting from the reverse stock split was rounded up to the nearest whole number of shares. Proportional adjustments were made to the number of shares of the Company's common stock issuable upon exercise or conversion of the Company's equity awards, warrants and other convertible securities, as well as the applicable exercise or conversion price thereof.

Accordingly, on February 28, 2023, the Company received official notice from Nasdaq that the Company evidenced compliance with all applicable criteria for continued listing on The Nasdaq Capital Market, including the $1.00 bid price requirement. As previously disclosed, the Company was granted an extension by the Nasdaq Hearings Panel through February 23, 2023 to regain compliance with the $1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2).