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, 2018**

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, NY	**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 Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Exchange 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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting 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 is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes☐ No ☑

As of June 29, 2018, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based on the average bid and asked price of the common equity on such date, was approximately $18.2 million. For purposes of this computation only, all officers, directors and 10% or greater stockholders of the registrant are deemed to be affiliates.

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of April 15, 2019 was 4,076,552 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement on Schedule 14A to be furnished to stockholders in connection with its 2019 Annual Meeting of Stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

NANOVIBRONIX, INC.

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PART I

ITEM 1. BUSINESS

Cautionary Note Regarding Forward-Looking Statements

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 risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- Our ability to continue as a going concern.
- The delisting of our common stock from the NASDAQ Capital Market.
- The timing of clinical studies and eventual U.S. Food and Drug Administration approval of our product candidates.
- Regulatory actions that could adversely affect the price of or demand for our approved products.
- Market acceptance of existing and new products.
- Favorable or unfavorable decisions about our products from government regulators, insurance companies or other third-party payers.
- Our intellectual property portfolio.
- Our ability to recruit and retain qualified regulatory and research and development personnel.
- 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.
- Our ability to generate internal growth.
- Changes in our relationship with key collaborators.
- Changes in the market valuation or earnings of our competitors or companies viewed as similar to us.
- Our failure to comply with regulatory guidelines.
- Uncertainty in industry demand and patient wellness behavior.
- General economic conditions and market conditions in the medical device industry.
- 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, wound healing and pain therapy and can be administered at home, without the assistance of medical professionals. Our primary products, which are in various stages of clinical and market development, currently consist of:

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

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

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

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

PainShield is currently cleared for marketing in the United States by the U.S. Food and Drug Administration although to date there has not been a significant sales and marketing effort. All three of our products have CE Mark approval in the European Union, and a certificate allowing us to sell PainShield, UroShield and WoundShield in Israel. We are able to sell PainShield, UroShield and WoundShield in India and Ecuador based on our CE Mark. We have consummated sales of PainShield and UroShield in the relevant markets, although to date sales have been minimal; WoundShield has not generated significant revenue to date. Outside of the United States we generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

In the United States, PainShield requires a prescription from a licensed healthcare practitioner. If U.S. Food and Drug Administration clearance is obtained, we anticipate that WoundShield and UroShield will require a prescription from a licensed healthcare practitioner in the United States. We anticipate that UroShield will be sold directly to health care facilities and therefore will not require a prescription for these venues. However, in other countries in which we sell PainShield, UroShield, and WoundShield, such products are eligible for sale without a prescription. We are working toward a new PainShield 510(k) submission which would potentially remove the requirement for a prescription.

In addition to the need to obtain regulatory approvals, we anticipate that sales volumes and prices of our UroShield, PainShield, and WoundShield products will depend in large part on the availability of insurance coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid in the United States, private insurance plans and workers' compensation plans. We do not currently have reimbursement codes for use of WoundShield in any of the markets in which we have regulatory authority to sell WoundShield. Of the markets in which we have regulatory authority to sell PainShield, we have reimbursement codes in the United States (i.e., CPT codes) for clinical use only, but do not have such reimbursement codes for at-home use of the product, although the product is marketed and sold for such use. 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 anticipate that we will begin to seek reimbursement codes for use of our products in the markets in which we have regulatory authority to sell such products; however, additional clinical data will be required in order to obtain such reimbursement codes. 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, Redemption Revenue Cycle Solutions, LLC, to help facilitate private insurance reimbursement.

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

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

The Company is beginning a study which is intended to assess the PainShield's ability to effectively treat Lateral Epicondylitis (Tennis Elbow). This is a double blinded, randomized control trial. The study in ongoing, but intended to enroll 24 patients.

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

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

Business Model

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

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

Ultrasound Technology and Our Products

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

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

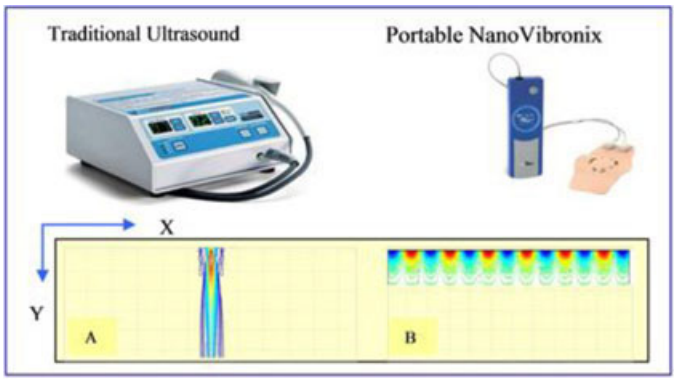
While there are currently a number of products on the market that treat pain through ultrasound therapy, we believe that our products differentiate themselves because they are portable, without the requirement to be plugged into an outlet and they have a frequency of 100kHz (in contrast to other devices, which have a frequency of 1MHz), which means our products do not produce heat that can damage tissue. Our products can therefore (i) be self-administered by the patient without the need to be moved about the treated area by the patient or a clinician, (ii) be applied for a significantly longer period without the risk of tissue damage and (iii) do not require the use of gel. We are aware of one competitive product with similar ultrasound technology, the SAM® Sport4 by a company called Zetroz Systems LLC, aka ZetrOz, Inc. However, it is our belief that this product does not generate surface acoustic waves as our products do, the treatment area is generally limited to that of the transducer's diameter, the use of transmission gel is still required and the transducer thickness is significantly greater than ours (approximately 1.5cm). To our knowledge, the device only provides a battery life of 4 hours and is continuous therapy versus intermittent therapy. We are also aware of a small clinical study, for which results were reported in August 2013, in which the SAM® Sport4 showed positive results in the treatment of venous ulcers, a type of chronic wound.

Research has further shown that ultrasound therapy has resulted in increased collagen repair (Da Cunha A, Parizotto NA, Vidal BC, "The effect of therapeutic ultrasound on repair of the achilles tendon (tendo calcaneus) of the rat", Ultrasound Med. Biol. 2001 December; 27(12):1691-6), improved resolution of inflammation (Young SR, Dyson M, "Macrophage responsiveness to therapeutic ultrasound", Ultrasound Med. Biol. 1990; 16(8):809-16) and increased tissue healing (Young SR, Dyson M, "Effect of therapeutic ultrasound on the healing of full-thickness excised skin lesions", Ultrasonics. 1990 May; 28(3):175-80), which are all important factors in the wound healing process. Furthermore, research has shown that ultrasound therapy can contribute to increased membrane permeability (Sundaram J, Mellein BR, Mitragotri S, "An experimental and theoretical analysis of ultrasound-induced permeabilization of cell membranes," Biophys. J. 2003 May; 84(5):3087-101) and accelerated fibrinolysis, a process that prevents blood clots from growing and becoming problematic (Harpaz D, "Ultrasound enhancement of thrombolytic therapy: observations and mechanisms", Int. J. Cardiovasc Intervent. 2000 June; 3(2):81-89), which collectively improve the tissue regeneration process and healing of wounds. Sonophoresis, a process that increases the absorption of semisolid topical compounds, including medications, into the skin, is an additional significant effect of ultrasound therapy (Tezel A, Paliwal S, Shen Z, Mitragotri S, "Low-frequency ultrasound as a transcutaneous immunization adjuvant", Vaccine 2005 May 31; 23(29):3800-7).

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

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

While there are currently a number of products on the market that treat pain through ultrasound therapy, we believe that our products differentiate themselves because they are portable, without the requirement to be plugged into an outlet and they operate with a frequency of 100kHz (in contrast to other devices, which have a frequency of 1MHz), which means our products do not produce heat that can damage tissue. Our products can therefore (i) be self-administered by the patient without the need to be moved about the treated area by the patient or a clinician, (ii) be applied for a significantly longer period without the risk of tissue damage and (iii) do not require the use of gel. We are aware of one competitive product with similar ultrasound technology, the SAM® Sport4 by a company called Zetroz Systems LLC, aka ZetrOz, Inc. However, it is our belief that this product does not generate surface acoustic waves as our products do, the treatment area is generally limited to that of the transducer's diameter, the use of transmission gel is still required and the transducer thickness is significantly greater than ours (approximately 1.5cm). To our knowledge, the device only provides a battery life of -four hours and is continuous therapy versus intermittent therapy. We are also aware of a small clinical study, for which results were reported in August 2013, in which the SAM® Sport4 showed positive results in the treatment of venous ulcers, a type of chronic wound.



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

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

Micro Vibrations Technology and Our Products

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

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

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

Our Products

Product Design, Packaging, Identity

All products have been redesigned with an updated look and improved performance. These new designs were coupled with new branding, packaging, instructional manuals, and marketing materials.

UroShield

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

Picture of UroShield with actuator

We believe the UroShield system has the following advantageous effects:

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

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

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

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

UroShield has undergone a number of clinical trials. The Heidelberg 1 trial, 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, 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.

Market for UroShield

Approximately 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.

Catheter acquired urinary tract infection (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).

According to a report by Zion Market Research, the global catheter market totaled approximately $26.6 billion in 2015 and is estimated to grow at a CAGR of 9.7% through 2021. In the United States there are 25 million Foley catheters sold annually and there are 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 $675 per case, and the cost of treating bacteremia has been estimated at $3,800 per case, yielding a total healthcare burden of $830 million per year. While there are currently both antibiotic and silver coated catheters in the market, they often sell for approximately $10 above the non-antimicrobial equivalent.

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

Competition for UroShield

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

UroShield has been designed to be added to any type of catheter, including Foley catheters and silver-coated catheters, to improve a catheter's infection prevention performance. UroShield is not intended to replace any existing products or technologies, but instead is intended to assist these existing products or technologies in preventing catheter-acquired urinary injury and catheter associated complications. UroShield may be unable to successfully compete in this market due to an inability to obtain clearance from the U.S. Food and Drug Administration and failure to be adopted by health care practitioners and facilities.

Regulatory Strategy

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

In the European Union, UroShield has been marketed for the prevention of biofilm, decreased pain and discomfort associated with urinary catheters and increased antibiotic efficacy.

In the United States, we intend to seek clearance from the U.S. Food and Drug Administration through the de novo classification process for UroShield. We submitted our application for 510(k) clearance on January 3, 2011. On March 11, 2011, we received a response from the U.S. Food and Drug Administration proposing that the approval go through the de novo route, which will require clinical trials with proposed study protocols to be pre-cleared by the U.S. Food and Drug Administration. We are currently seeking a strategic partner that is active in the urology market to coincide with the U.S. Food and Drug Administration clearance. We have not made any further submissions to the U.S. Food and Drug Administration related to UroShield, but we recently completed a more robust study conducted at 5 different nursing facilities in the United States. This study was approved by the institutional review board, or "IRB". In November 2017, we announced interim results of this study.

NanoVibronix filed a request for a teleconference with FDA reviewers to understand the suitability of determining the medical device accessory classification via a de novo petition and to understand the expectations in order to establish safety and efficacy of UroShield. In the FDA's written response and also during the teleconference, the FDA reviewers stated that they were particularly concerned with local tissue response (in urethra and potentially bladder) due to the extended use (up to 30 days) of a urinary catheter with UroShield attached to it. The areas of concern were primarily the physical interaction of ultrasound that is being propagated along the walls of the catheter and any leachables from the urinary catheter that would be over and above the leachables from a urinary catheter without UroShield attached to it. FDA reviewers were also concerned about the appropriateness and quality of safety test data that was previously submitted May 2012.

Studies being conducted to establish safety of UroShield for human use:

A large animal model (female sheep) study will be 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.

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

Sales and Marketing

We believe the business opportunity for UroShield is in the hundreds of millions in U.S. dollars to the extent that UroShield obtains 510(k) clearance from the U.S. Food and Drug Administration, is recognized as effective and becomes widely adopted for use in catheters. To that end, we are exploring sales distribution models in the United States through a distributor network and direct sales. In order to have a distribution network in place if UroShield receives clearance from the U.S. Food and Drug Administration, we are currently identifying distributors through several vehicles, including our sales staff, commissionable representation, and independent contractors. We have recently appointed distributors for UroShield in the United Kingdom and, and an outside management organization, Morulaa Health, to assist with regulatory matters and distribution of UroShield in India. Each of these distributors is paid a small retainer and will be paid a commission between 10 to 20% of sales going forward.

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

Clinical Trials

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

Purpose	Doctor/Location	Time, subjects	Objectives	Results
To assess the safety of the UroShield Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD1)	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2005-2006 22 patients	To demonstrate that the use of the UroShield is safe and that the device is well tolerated by the patients and user friendly to the medical staff. Efficacy objectives were to demonstrate that the UroShield helps in prevention of biofilm formation in comparison with the urinary catheter alone, as well as bacteriuria.	UroShield was both safe and well tolerated. UroShield proved efficacious in prevention of biofilm. Subjects required significantly less medications than the control group for catheter related pain and discomfort.
Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD2 **)** Physician initiated	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2007 40 patients	To demonstrate that the use of the UroShield is safe and helps in prevention of biofilm formation and UTI in comparison with the urinary catheter alone, as well as decrease antibiotic use.	In this trial, only 1/20 patients in UroShield device (no antibiotics) group developed urinary tract infection compared to 4/20 patients within control group treated with the antibiotic prophylaxis alone.
The Effect of UroShield on Pain and Discomfort in Patients Released from the Emergency Room with Urinary Catheter Due to Urine Incontinence Physician initiated	Shaare Zedek Medical Center Jerusalem, Israel.	2007 10 patients	The study aimed to assess the effectiveness of the UroShield in reducing pain and discomfort levels and improve the well-being of the subjects. Efficacy objectives included reduction of pain, spasm, burning and itching sensation levels of the subjects.	The results demonstrated a reduction in pain, itching, burning and spasm levels. Additionally, the well-being of the subjects showed a significant increase.
The Use of the UroShield Device in Patients with Indwelling Urinary Catheters Open labeled, comparative, randomized study	Dr. Shenfeld Shaare Zedek Medical Center Jerusalem, Israel.	2007-2009 40 patients	Patient complaints related to catheter regarding pain according to VAS scale and discomfort according to 0-10 scale Presence of Clinically Significant UTI Presence of Bacteriuria Presence of Biofilm Use of medication	UroShield device was effective in reducing postoperative catheter related pain discomfort and bladder spasms. There was also a notable trend towards reduction of bacteriuria.
Evaluation of the UroShield in urinary and nephrostomies to reduce bacteriuria Physician initiated	Prof. P.Tenke, Hungary	2010-2011 27 patients	● Pain, disability and QOL ● Catheter patency ● Bacteriuria / UTI ● Hospitalization period ● Analgesics and Antibiotics intake	Showed reduction in pain and significant decrease in bacteriuria rate.

Double Blind, Randomized Control Study for Prevention of Bacterial Colonization and UTI associated with Indwelling Urinary Catheters	Dr. Shira Markowitz Buffalo, NY	2017 55 patients	To demonstrate the use of the UroShield reduces bacterial colonization on the urinary catheter	Final results entitled “The Effect of Surface Acoustic Waves on Bacterial Load and Preventing Catheter-Associated Urinary Tract Infections (CAUTI) in Long Term Indwelling Catheters,” which was published in the December 2018 issue of Medical & Surgical Urology, a leading peer-reviewed journal in the field of urology. Mean improvement advantage in treatment vs control was 87.2K CFU, (t (53) 18.1, $p<0.001$) at thirty days. At 60 days the mean improvement advantage in treatment vs control was 87.5K CFU, (t (53) 18.1, $p<0.001$). At 90 days the mean improvement advantage in treatment vs control was 79.3K CFU, (t (53) 12.4, $p<0.001$). After cessation of treatment in the active group at 30 days, there was a minimal increase in CFU count at both 60 and 90 days. In the same group, there was no statistical difference in the decrease of CFU count from 30 to 60 days after treatment, t (28)=1. p= ..326, however there was a marginally significant increase in CFU from 60 to 90 days for the active group (28)=1.7 p= 0.09. At baseline, every enrolled patient had been treated for infection during the 90 days prior to enrollment. Compared to baseline, the treatment group showed significant statistical and clinical improvement (100%) at 30 days relative to the sham control (73%). There were no reported infections in the Treatment Group while in the control group there were seven reported infections. At 90 days after treatment, the treatment group showed a significantly stronger improvement (89.7%) compared to the sham control (46.2%). There were three reported infection in the Treatment group, while in the control group there were fourteen reported infections requiring antimicrobial therapy. (logistic regression B=2.3, Wald Chi-Square (df=1) =10.1, p=0.001.)

Current, Ongoing and Planned Clinical Trial

UroShield Randomized Control trial (Completed)-A 56 patient trial was completed in January 2018, with compelling results, proving a decrease in both bacterial colonization and the incidence of Urinary Tract Infection. As issued in a press release depicting interim results, the following was noted:

"The trial was conducted at 5 different nursing facilities, in which 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 antibiotics.

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."

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 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.

A 23 patient trial was completed recently in Norwich, United Kingdom. The trial was initiated to satisfy the requirements for adoption within the UK National Health Service. Results of the trial are not yet known.

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

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

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

Patients with neurogenic bladder dysfunction (spinal cord injury, or multiple sclerosis) have significant urinary morbidity. While intermittent catheterization is the preferred management method with there is a need to supplement bladder emptying, up to 30-50% use indwelling catheters due to their convenience and due to limitations around the performance of CIC. Urinary tract infections are common, and a defined source of mortality in this population. Patients with neurogenic bladder are unique compared to the general population in that they often have intrinsic bladder dysfunction (impaired compliance, impaired innate immunity, and neurogenic detrusor overactivity) and colonization with atypical and pathogenic bacteria. Additional urinary symptoms related to the indwelling catheter can include bladder discomfort, sediment and catheter bypassing, and systematic symptoms (autonomic dysreflexia among patients with spinal cord injury). There are limited management options for patients with indwelling catheters and bladder symptoms or frequent UTIs and there is a need for additional therapies that can mitigate these symptoms.

This study will be done without cost to NanoVibronix and is expected to be presented at the International Neurology Meeting in Zurich in January, or worst case, American Urologic Association in the fall.

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

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

PainShield®

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

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

Picture of PainShield with Patch

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

Market for PainShield

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

Competition

There are numerous products and approaches currently utilized to treat chronic pain. The pharmacological approach, which may be the most common, focuses on drug-related treatments with the over-the-counter internal analgesic market estimated at $3.8 billion in 2013. 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, which has recently received U.S. Food and Drug Administration approval and also has CE Mark approval, marketed by ZetrOZ, Inc., that we understand may eliminate certain of these requirements and limitations, namely the requirement to be plugged in, the need for movement around the treated area and the relatively short safe treatment period. However, we understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that under the transducer, that the use of transmission gel is still required and that the transducer thickness is significantly greater than ours (approximately 1.5cm). It is also our understanding that the U.S. Food and Drug Administration has prohibited the manufacturer from labeling or promoting this product for use directly over bone that is near the skin surface. In addition, there are other patch-based methods of pain treatment, such as TENS therapy. TENS therapy may be painful and irritating for the patient due to the muscle contractions resulting from the electrical pulses. PainShield combines the efficacy of ultrasound treatment for pain with the ease of use and portability of a patch-based system. PainShield also may be self-administered by the patient, including while the patient is sleeping. However, if we are unable to obtain widespread insurance coverage and reimbursement for PainShield, its acceptance as a pain management treatment would likely be hindered, as patients may be reluctant to pay for the product out-of-pocket.

Regulatory Strategy

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

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

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

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

Sales and Marketing

PainShield was introduced in 2009 as a treatment for pain, such as tendonitis, sports injuries, pelvic pain and neurologic pain and we have sold approximately 1,700 units and 15,000 treatment patches since its introduction. We have entered into distribution agreements in United States, Europe, Asia and India for the distribution of PainShield. We intend to seek additional distribution opportunities in Europe, East Asia and Ecuador. In addition, we sell PainShield directly to patients through our website. We are currently ramping up our marketing efforts in the US market and throughout the world. We anticipate that these efforts will include recruiting additional sales personnel and representatives, making in-office calls to physicians and attending trade shows and conferences. We intend to pursue the veterinary market with our equine PainShield device.

We have identified a unique and effective application for PainShield, the treatment of a severe facial nerve pain called Trigeminal Neuralgia, otherwise known as tic douloureux. Two studies were performed in Israel, "a randomized control trial examining the efficacy of low intensity low frequency Surface Acoustic wave ultrasound in trigeminal neuralgia pain", and "A sound solution for Trigeminal Neuralgia". Two trials which enrolled a total of 16 and 15 patients respectively, both conducted at the Sheba Medical Center in Israel, concluded that this study supports the hypothesis that the application of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound (LILF/SAW) may be associated with a clinically significant reduction of pain severity among patients suffering from trigeminal neuralgia disease. One of the studies showed a reduction in pain among 73% of the participants. We believe this to be an ideal market to address with the PainShield. With few existing treatment alternatives, we believe the PainShield's effectiveness is a practical and safe alternative. A broader RCT, targeting 60 patients suffering from unilateral trigeminal neuralgia, was recently completed. The article will be completed and ready for submission within 90 days.

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 plan to aggressively pursue this market through direct marketing efforts and distributor relationships.

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

Recently Completed Research

A double-blind randomized control trial of a PainShield Surface Acoustic Wave Patch, the patch used in conjunction with the PainShield device, was completed in the first quarter of 2018.

After the enrollment and lead-in period, subjects were given a sham device to sleep with every night for a month. They were asked to fill out their pain and analgesic use logs, and undergo the bi weekly assessments. After a month they were crossed over to an active "PainShield SAW patch device" and continued to complete their pain and analgesic use logs as well as undergo biweekly assessments for months two and three of the study.

In the first quarter of 2019, the double blinded, crossover trial was conducted across the US 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 that were assessed include Visual Analog Scale (VAS) pain score, both baseline prior to trial and VAS pain score at the end of the study. The study also assessed breakthrough medications per week at the start of the trial and breakthrough medications per week at the end of the trial, with a particular focus on the use of opioids. Breakthrough medications are used for chronic pain directly related to the pre-existing Trigeminal Neuralgia condition.

There was a significant difference in the outcomes of the two groups relative to pain, quality of life, and breakthrough medications taken, which was directly correlated to pain experienced during treatment. Specifically, the 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. In addition to measurable differences in all aforementioned measurement categories, there was a general improvement in uninterrupted sleep.

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 ●To assess the injury status ●To assess the efficacy of the treatment ●To assess compliance factors	Active group: 74% had improvement, 26% no change Sham group: 56% no change, 44% had improvement This is an indication of the effectiveness of the device. Lack of funding for statistical analysis has stopped this trial prior to fulfillment.
Reduction of chronic abdominal and pelvic pain, urological and GI symptoms using wearable device delivering low frequency ultrasound	D. Wiseman, Synechion Institute for Pelvic Pain	2011 19 patients	●To assess the efficacy of PainShield for pelvic and related pain	Improvement in pain related symptoms noted for all symptoms.
PainShield for Trigeminal Neuralgia	Shira Markowitz, MD, New York, NY	Early 2018 60 patients	●To assess the efficacy of PainShield for treating trigeminal neuralgia	Interim results released in the fourth quarter of 2017, which reported improvement in pain and quality of life; final results expected to be reported in the second quarter of 2018

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

We announced interim results of a study entitled, "The Effects of the NanoVibronix's PainShield® Surface Acoustic Waves on the Symptoms of Lateral Epicondylitis." The clinical study was conducted by Dr. David Lemak, a leading orthopedic surgeon with Birmingham Orthopedic and Sports Specialists.

The trial was 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"). A total of 24 patients were enrolled, half of whom were treated with the PainShield™ device plus physical therapy and the other half were treated with a placebo device plus physical therapy. Two of the patients did not complete the trial. Patients were not allowed to use opioids during the trial, nor were they allowed to have any type of injections (cortisone or any other) at any time during the study or within the last 30 days. Patients were allowed to take standard over-the-counter anti-inflammatory medication such as ibuprofen.

While the study is ongoing with additional patients enrolling, based on the initial results, seven out of ten patients (70.0%) who completed the study using PainShield plus physical therapy had complete resolution or significant improvement in pain. Among the placebo group plus physical therapy, five out of twelve patients (41.7%) experienced complete resolution or significant improvement in pain. Upon completion of the trial, the Company will have full results, which it expects to publish later this year.

WoundShield®

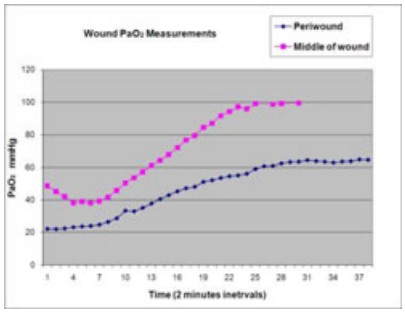
Our WoundShield product was granted the European Wound Closure Customer Value Leadership Award, Ultrasound Therapy – Wound Closure in 2014. WoundShield is intended to treat acute and chronic wounds with a disposable treatment patch that delivers localized therapeutic low frequency ultrasound. The WoundShield 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).

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. Recently, wound healing experts have developed a technique of perfusing ischemic wounds (which occur when blood flow is blocked) with hyper-oxygenated saline, while the wound is being treated with ultrasound, also known as sonication. This localized oxygenation therapy has many advantages over the use of hyperbaric chambers (large chambers in which the oxygen pressure is above normal), a common method for delivering oxygen to wounds, as it is more cost-effective, can be done at the patient's bedside and can be administered more frequently. The WoundShield instillation patch was tested as a potential ultrasound technology for this localized oxygen therapy. In one study (Morykwas M, "Oxygen Therapy with Surface Acoustic Waveform Sonication," European Wound Management Association 2011; we supplied devices for this study, but had no further involvement with it), oxygen sensors were placed in the wound bed to directly measure partial pressure of oxygen in an ischemic wound bed on a pig. The wound was perfused with hyperbaric oxygen and sonicated using the WoundShield instillation patch. With surface acoustic wave ultrasound technology, tissue oxygen levels (partial pressure of oxygen in the blood, or PaO2) were raised from a range of 20 mmHg (millimeters of mercury) to 60 mmHg in peripheral (periwound) areas, a 3 centimeter distance away from the transducer, and from 40 mmHg to greater than 100 mmHg in the central wound bed lying below the WoundShield instillation patch (see table below). The results of this study illustrated that the WoundShield instillation patch allowed oxygen to directly enter into the wound. The direct entry of the oxygen increased the amount of oxygen reaching the wound, which has been shown to advance the healing process. In addition, we believe that WoundShield's small size, lower cost and ease of use makes localized oxygen treatment commercially viable.



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

Market for Wound-Healing Devices

The global wound care device market totaled approximately $24 billion in 2015 and it is expected to grow at a CAGR of 6.7% during 2016-2022 (as reported by P&S Global Research in January 2017). According to the Global Report on Diabetes produced by the World Health Organization 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., 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. Based upon currently available information about this device, we believe it will be at least 2018 before this device is available on the market for treatment of venous ulcers. 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 do not believe that the WoundShield instillation patch will necessarily compete with hyperbaric chamber therapy, but rather will often complement such therapy.

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

Regulatory Strategy

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

Our general regulatory strategy for WoundShield is focused on seeking U.S. Food and Drug Administration approval for a variety of indications. WoundShield obtained CE Mark approval in November 2012.

Sales and Marketing

WoundShield has generated minimal revenues to date. We intend to market WoundShield in Europe and pursue the necessary approvals to commence marketing in the United States and Canada. Our strategy for selling WoundShield in the United States is to find a strategic partner in the wound care market. We are actively pursuing this strategy. WoundShield could be an effective adjunct to existing wound treatment devices or a stand-alone wound treatment modality.

Clinical Trials

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

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

Third Party Reimbursement

NanoVibronix has entered into an agreement with Redemption Revenue Cycle Solutions LLC, beginning on January 1, 2019. RRCS has an expertise in establishing reimbursement at a reasonable rate, and facilitating the billing for both NanoVibronix and its distributors.

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans and workers' compensation plans, among others. These third party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse health care providers who use the products or therapies. Even though a new product may have been approved or cleared by the U.S. Food and Drug Administration for commercial distribution, we may find limited demand for the device until adequate reimbursement has been obtained from governmental and private third party payers.

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

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

One of the components in the reimbursement decision by most private insurers and governmental payers, including the Centers for Medicare and Medicaid Services, which administers Medicare, is the assignment of a billing code. Billing codes are used to identify the procedures performed when providers submit claims to third party payers for reimbursement for medical services. They also generally form the basis for payment amounts.

Obtaining reimbursement approval for a product from any government or other third party payer is a time-consuming and costly process that could require us or our distributors to provide supporting scientific, clinical and cost-effectiveness data for the use of our product to each payer. Even if a code is obtained for a product, a third party payer must still make coverage and payment determinations. When a payer determines that a product that 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, recent health care reform measures, as well as legislative and regulatory initiatives at the federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third party payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

UroShield. We expect these products to be used in inpatient settings and therefore reimbursed under the 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 pursue reimbursement in the Medicare Part B code to support the use for long term catheter use and infection prevention in the home.

PainShield. Although it is a minimal amount, PainShield is presently reimbursed in the United States by many private insurers under the national umbrella for diathermy service, CPT code 97024, for use of the ultrasound device in a supervised medical setting and is reimbursed in 15-minute increments for up to an hour a day, 5 hours a week and 20 hours a month. The current reimbursement mechanism is inadequate to support the end user or distributor cost of the device. If the device is efficacious in the treatment of the patient's condition, the treatment period can be extended in some cases for months. Presently, when used in an outpatient setting, such as by a clinic, PainShield is typically purchased by the clinic that then can bill the existing reimbursement codes. PainShield is not currently reimbursed for therapy in the home setting. When we have sufficient funding, we intend to work to obtain reimbursement in the home setting as well as codes that would allow for reimbursement for use of the non-disposable and disposable components of the PainShield device. Our anticipated clinical trials for PainShield would support this effort. In the United States, PainShield requires a prescription from a physician.

WoundShield. We believe that the initial usage of these products will be in the hospital setting. Reimbursement in the hospital setting is typically governed by the Diagnosis Related Group system, or DRG system, which is a prospective payment methodology that assigns a predetermined, fixed amount based on the patient's diagnoses. In parallel to introducing these devices to hospitals, we intend to apply for reimbursement codes for outpatient use. Although obtaining these codes can take years and may require extensive clinical data, we believe that the desirable characteristics of these products may serve as an incentive to insurance companies to grant these codes more quickly.

New Products Under Development

Renooskin

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

LungShield

A pilot study, adapting the UroShield technology to endotracheal tubes, is currently underway at Shaare Zedek Medical Center. The purpose of this study is to examine the effect of a device which generates low energy ultrasound waves like the UroShield product. The endpoint of the study is to show its effect on development of bacterial colonies on endotracheal tubes, in patient receiving mechanical ventilation, and to determine whether this effect lowers the rate of bacterial resistance to antibiotics. Results of this study are not known at this time, and is still ongoing.

Research and Development Expenses

During the years ended December 31, 2018 and 2017, we spent approximately $614,000 and $693,000, respectively, on research and development activities. None of the cost of such activities is borne directly by our customers.

Intellectual Property

Patents

We have rights to six patents in the United States. Granted U.S. Patent No. 7,393,501 (having the following foreign counter-parts: China ZL03818327.7; Israel 165422; Japan 4504183; India 246351; Australia 2003231892; European Union 1511414 B), "Method, apparatus and system for treating biofilms associated with catheters" and granted U.S. Patent No. 7,829,029 (having the following foreign counter-parts: China ZL200780019732.3 and European Union 1998834), "Acoustic add-on device for biofilm prevention in urinary catheter," both relate to the use of surface acoustic waves to prevent biofilm formation on indwelling catheters. These granted U.S. patents expire on December 19, 2023 and October 27, 2025, respectively. Granted U.S Patent No. 9,028,748, "System and method for surface acoustic wave treatment of medical devices," relate to methods of generating surface acoustic waves on medical device surfaces on both indwelling medical devices and implants to prevent biofilm formation This U.S. patent expires on July 11, 2030. Granted U.S. Patent No. 9,585,977 (having the following foreign counter-parts: China ZL200780014875.5, European Union, and allowed Israel application), "System and method for surface acoustic waves treatment of skin," relates to methods of using surface acoustic waves for treatment of skin for the purpose of wound-healing, reducing infection, pain reduction and cosmetic enhancements. This U.S. patent expires August 20, 2033.

We also license two in-force patents pursuant to a license agreement with Piezo-Top Ltd and PMG Medica Ltd., U.S. Patent No. 6,454,716 B1, "System and method for detection of fetal heartbeat," and U.S. Patent No. 6,964,640 B2, "System and method for detection of motion," which incorporate certain technology related to detecting in-vivo motion relating to biological parameters such as, for example, blood flow detection, heartbeat monitoring, fetal motion monitoring, fetal heartbeat monitoring, etc.. The configuration allows for an optimal scanning range at an unlimited number of angles. These patents expire on May 23, 2020 and January 22, 2023, respectively.

We believe the granted patents, patent applications and license agreement (described below) collectively cover our existing products to the extent necessary, and may be useful for protecting our future technology developments. We intend to continue patenting new technology as it is developed, and to actively pursue any infringement of any of our patents.

To date, we are not aware of other companies that have patent rights to a comparable system and method for surface acoustic wave treatment for skin.

Trademarks

We believe that our product brand names are an important factor in establishing and maintaining brand recognition. We have the following trademark registrations in the United States: NanoVibronix®, WoundShield®, PainShield®, and UroShield®. We intend to re-file and pursue our previously acquired trademark registration "Curing though prevention"®, which expired in July 2015. Generally, the protection afforded for trademarks is perpetual, if they are renewed on a timely basis, if registered, and continue to be used properly as trademarks.

Government Regulation

U.S. Food and Drug Administration Regulation

Each of our products must be approved, cleared by, or registered with the U.S. Food and Drug Administration before it is marketed in the United States. Before and after approval or clearance in the United States, our products, approved or cleared products and product candidates, are subject to extensive regulation by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. The U.S. Food and Drug Administration regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products. PainShield has already obtained 510(k) marketing approval by the U.S. Food and Drug Administration.

U.S. Food and Drug Administration Approval or Clearance of Medical Devices

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

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

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

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device, has the same intended use, and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the U.S. Food and Drug Administration issues a clearance letter finding substantial equivalence. The typical duration to receive 510(k) approval is approximately nine months from the date of the initial 510(k) submission, although there is no guaranty that the timing will not be longer.

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

After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the U.S. Food and Drug Administration determines that the product does not qualify for 510(k) clearance, then a company must submit and the U.S. Food and Drug Administration must approve a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive nonclinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the U.S. Food and Drug Administration will inspect the manufacturer's facilities for compliance with quality system regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the U.S. Food and Drug Administration determines the application or manufacturing facilities are not acceptable, the U.S. Food and Drug Administration may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the U.S. Food and Drug Administration ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, a U.S. Food and Drug Administration advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the U.S. Food and Drug Administration whether, or upon what conditions, the device should be approved. The U.S. Food and Drug Administration is not bound by the advisory panel decision. While the U.S. Food and Drug Administration often follows the panel's recommendation, there have been instances where the U.S. Food and Drug Administration has not. If the U.S. Food and Drug Administration finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. The typical duration to receive PMA approval is approximately two years from the date of submission of the initial PMA application, although there is no guarantee that the timing will not be longer.

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

Clinical Trials of Medical Devices

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

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

Post-Approval Regulation of Medical Devices

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

- the U.S. Food and Drug Administration quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- the Medical Device Reporting regulation, which requires reporting to the U.S. Food and Drug Administration of certain adverse experiences associated with use of the product.

Good Manufacturing Practices Requirements

Manufacturers of medical devices are required to comply with the good manufacturing practices set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act as further set forth in the Code of Federal Regulations as 21 CFR Part 820. Current good manufacturing practices ("cGMP") regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for an approved product must meet current good manufacturing practices requirements to the satisfaction of the U.S. Food and Drug Administration pursuant to a pre-PMA approval inspection before the facility can be used. Manufacturers, including third party contract manufacturers, are also subject to periodic inspections by the U.S. Food and Drug Administration and other authorities to assess compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer, and possibly us, to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the U.S. Food and Drug Administration and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

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

The primary regulatory environment in Europe is the European Union, which consists of 25 member states and 42 competent authorities encompassing most of the major countries in Europe. In the European Union, the European Medicines Agency and the European Union Commission determined that PainShield, UroShield, and WoundShield are to be regulated as medical device products. These products are classified as Class II devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area. We are required to be recertified each year for CE by Intertek, which conducts an annual audit. The audit procedure, which includes on-site visits at our facility, requires us to provide Intertek with information and documentation concerning our management system and all applicable documents, policies, procedures, manuals, and other information.

The primary regulatory bodies and paths in Asia, Australia, and Latin America are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485, requirements for quality management systems published by the International Organization of Standardization. In some countries outside Europe, we are or will be able to sell on the basis of our CE Mark. We have the Health for PainShield, WoundShield and UroShield, a certificate by the Israel Ministry of Health allowing us to sell PainShield, WoundShield and UroShield in Israel, a certificate allowing us to sell PainShield in Australia, and we are able to sell PainShield, WoundShield and UroShield in India and Ecuador based on our CE Mark. In addition, our distributor in Korea has applied for approval to sell PainShield and UroShield. We generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

European Good Manufacturing Practices

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

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

In the United States, federal and state fraud and abuse laws prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of health care products and services. Other provisions of federal and state laws prohibit presenting, or causing to be presented, to third party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, other health care laws and regulations may apply, such as transparency and reporting requirements, and privacy and security requirements. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal and state health care programs. These laws are potentially applicable to manufacturers of products regulated by the U.S. Food and Drug Administration as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. The health care laws that may be applicable to our business or operations include:

- The federal Anti-Kickback Statute, which prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other federal health care program.

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

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

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

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

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

Customers

We currently sell our products both through our website and distribution agreements, with approximately 55% of our sales coming through distributors in 2018. We expect that percentage to grow significantly as we enter into additional distribution agreements. We have exclusive and non-exclusive distribution agreements for our products with medical product distributors based in the United States, various countries throughout Europe, India, and Asia.

We are currently in discussions with a number of distribution companies in the United States, Europe, and Asia, as well as a distributor which will allow access into 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.

Manufacturing and Suppliers

We have traditionally assembled our products in-house at our facilities in Nesher, Israel. All of the component parts of our products are readily available from a number of manufacturers and suppliers. We order component parts on an as-needed basis, generally from the manufacturer that provides us with the most competitive pricing. Our most significant suppliers are APC International, Ltd., R&D Medical Products, DI-EL Tack Ltd., Rotel Product Engineering Ltd. and Afinity. We do not have written agreements with any of these suppliers, but we believe anyone could be easily replaced if necessary.

In December 2018, we announced we appointed Quasar as contract manufacturer for the PainShield®, UroShield®, WoundShield® as well as other devices. Quasar (http://www.quasar-med.com/) is a medical device manufacturer with over 30 years of experience, serving major brands worldwide, with complex catheters, disposables, and U.S. Food and Drug Administration regulated assemblies. Quasar delivers a full lifecycle array of engineering services, including design-to-cost, jigs and tool design, as well as unique production process-design services that allow for the highest levels of efficiency and productivity. Quasar is ISO9001 and ISO13485 certified, as well as U.S. Food and Drug Administration registered.

Recent Developments

In January, 2019, we began collaborating with the Fritz Clinic, which has been at the forefront of tackling the opioid epidemic. As a leader in the field of opioid addiction, the Company supports Dr. Fritz' approach in aiding patients with opioid dependence and providing them with alternative treatments to address the underlying cause of pain, rather than simply masking it with pain killers.

In February, 2019, we announced the publication of an independent study entitled, "The Effect of a Surface Acoustic Wave (SAW) Device on the Symptomatology of Trigeminal Neuralgia," which was published in the January 2019 issue of Journal of Anesthesiology and Pain Research, a leading peer-reviewed journal in the field of anesthesiology. The double blinded, crossover trial was conducted across the U.S. and included 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. In addition to measurable differences in all aforementioned measurement categories, there was a general improvement in uninterrupted sleep.

In March, 2019, the Company announced results of a study entitled, "The Effects of the NanoVibronix's PainShield® Surface Acoustic Waves on the Symptoms of Lateral Epicondylitis" (Tennis Elbow). While the study is ongoing with additional patients enrolling, based on the initial results, seven out of ten patients (70.0%) who completed the study using PainShield plus physical therapy had complete resolution or significant improvement in pain. Among the placebo group plus physical therapy, five out of twelve patients (41.7%) experienced complete resolution or significant improvement in pain. Upon completion of the trial, the Company will have full results, which it expects to publish later this year

Customers

We currently sell our products both directly, through our website, and indirectly via distribution agreements, with approximately 55% of our sales coming through distributors in 2018. We expect that percentage to grow significantly as we enter into additional distribution agreements. We have exclusive and non-exclusive distribution agreements for our products with medical product distributors based in the United States, in the United Kingdom and various countries throughout Europe, India, Canada and Asia.

We are currently in discussions with several distribution companies in the United States, Europe, and Asia, as well as a distributor which will allow access into 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.

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We assemble our products in-house at our facilities in Nesher, Israel. All of the component parts of our products are readily available from a number of manufacturers and suppliers. We order component parts on an as-needed basis, generally from the manufacturer that provides us with the most competitive pricing. Our most significant suppliers are APC International, Ltd., Tamuz Electronics, DI-EL Tack Ltd., Rotel Product Engineering Ltd. and Sinpro Electronics Co., Ltd. We do not have written agreements with any of these suppliers, but we believe anyone could be easily replaced if necessary.

Employees

At December 31, 2018, we had 10 full-time employees and four contract employees. In addition, we employ several consultants on an as needed basis, to provide a cost efficient alternative to a larger infrastructure to support the Company.

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 public may read and copy any materials filed by the Company with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the Company's references to website URLs are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

Risks Related to Our Business

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

For the fiscal year ended December 31, 2018 we had a net loss of approximately $4.2 million, with revenues of approximately $318,000. As of December 31, 2018, we had an accumulated deficit of approximately $32.5 million. We expect to incur losses for at least the next year, as we continue to incur expenses related to seeking U.S. Food and Drug Administration approval for UroShield and WoundShield, and market acceptance and reclassification of PainShield, which will require costly additional clinical trials and research, further product development and professional fees associated with regulatory compliance.

These conditions coupled with our current liquidity position raise substantial doubt about our ability to continue as a going concern. Even if we succeed in commercializing our new products, we may not be able to generate sufficient revenues to cover our expenses and achieve sustained profitability or be able to maintain profitability. If we are unable to raise additional capital, we may be forced to cease operations.

The report of our independent registered public accounting firm expresses substantial doubt about the Company's ability to continue as a going concern. Such "going concern" opinion could impair our ability to obtain financing.

Our auditors, Marcum LLP, have indicated in their report on the Company's financial statements for the fiscal year ended December 31, 2018 that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations. A "going concern" opinion could impair our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. Our ability to continue as a going concern will depend upon the availability and terms of future funding. If we are unable to achieve this goal, our business would be jeopardized and the Company may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment.

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 willseek 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.

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 fianncings by issuing equity securities, the percentage ownership of its existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders.

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

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

The availability and levels of reimbursement by governmental and other third party payers affect the market for our approved products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain reimbursement or pricing approvals in markets we seek to enter in a timely manner, if at all. Our failure to receive reimbursement or pricing approvals in target markets would negatively impact market acceptance of our products in these jurisdictions, placing us at a material cost disadvantage to our competitors.

Even if we obtain reimbursement approvals for our products, we believe that, in the future, reimbursement for any of our products or product candidates may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or policies of third party payers that limit reimbursement may adversely affect the demand for our products currently under development and our ability to sell our products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

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

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

Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products. We face competition from established medical device companies, such as Neurometrix Inc., Zetrox, Kinetic Concepts, Inc. and Smith & Nephew plc, manufacturers of certain portable ultrasound devices capable of self-administered use, as well as from academic institutions, government agencies, and private and public research institutions in the United States and abroad. Most, if not all, of our principal competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, marketing approved products, protecting and defending their intellectual property rights and designing around the intellectual property rights of others. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements, or mergers with, or acquisitions by, large and established companies, or through the development of novel products and technologies.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may be able to respond to changes in technology or the marketplace faster than us. Our competitors may develop and commercialize medical devices that are safer or more effective or are less expensive than any products that we may develop. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to our programs or advantageous to our business. Given our small size and lack of resources, we are often at a disadvantage with our competitors in all of these areas, which could limit or eliminate our commercial opportunities.

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

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

Our product candidates may not be developed or commercialized successfully.

Our product candidates are based on a technology that has not been used previously in the manner we propose and must compete with more established treatments currently accepted as the standards of care. Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use.

We are subject to the risks that:

- the U.S. Food and Drug Administration or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates.

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

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

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

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

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

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

Our success depends on our ability to attract, retain and motivate highly qualified management and personnel. As a small company with ten full-time employees and four contract employees, our success depends on the continuing contributions of our management team and qualified personnel and on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. We are also at a disadvantage in recruiting and retaining key personnel as our small size and limited resources may be viewed as providing a less stable environment, with fewer opportunities than would be the case at one of our larger competitors. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan. In addition, the replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

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

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

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

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

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

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

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

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

Risks Related to the Regulation of Our Products

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

The process of obtaining U.S. Food and Drug Administration approval is lengthy, expensive and uncertain, and we cannot be sure that our additional product candidates will be approved in a timely fashion, or at all. If the U.S. Food and Drug Administration does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers and our contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

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

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

- testing and quality control;

- manufacturing;
- quality assurance
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the U.S. Food and Drug Administration certain adverse experiences associated with the use of the products; and
- obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

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

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

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

International sales of our products and any of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the United States where we do not already possess regulatory approval will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging and labeling requirements, and import restrictions on medical devices. In addition, each country has its own tariff regulations, duties and tax requirements, as well as reimbursement and healthcare payment systems. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. We may be required to perform additional pre-clinical, clinical or post-approval studies even if U.S. Food and Drug Administration approval has been obtained. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

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

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

The adoption of health policy changes and health care reform in the United States may adversely affect our business and financial results.

On March 23, 2010, President Obama signed into law major health care reform legislation under the Patient Protection and Affordable Care Act of 2010, commonly referred to as the Affordable Care Act, which was modified on March 30, 2010, by the enactment of the Health Care and Education Reconciliation Act of 2010. The Affordable Care Act contains numerous regulations regarding the payment for and provision of health care, including provisions aimed at improving quality, extending health care coverage to tens of millions of individuals, enhancing remedies for fraud and abuse, adding transparency requirements and conditions to reimbursement, and decreasing health care costs. The Affordable Care Act also includes significant provisions that encourage state and federal law enforcement agencies to increase activities related to preventing, detecting and prosecuting those who commit fraud, waste and abuse in federal healthcare programs, including Medicare, Medicaid and Tricare. This legislation is one of the most comprehensive and significant reforms ever experienced by the United States health care industry and has significantly changed the way health care is financed by both governmental and private insurers. Extending health care coverage to those who previously lacked coverage will likely result in substantial cost to the United States federal government, which may force additional changes to the health care system in the United States. Much of the funding for expanded health care coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of health care and increased enforcement activities. The cost of health care could be reduced by decreasing the level of reimbursement for medical services or products (including products we may sell or market), or by restricting coverage of medical services or products. A reduction in the use of or reimbursement for products we may sell in the United States could materially adversely affect our business and results of operations.

Some of the provisions of the Affordable Care Act have not yet been fully implemented and the effect of the legislation is difficult to predict. The Affordable Care Act continues to be implemented through regulation and government activity, and is subject to possible additional implementing regulations and interpretive guidelines. Further, the Affordable Care Act has been subject to judicial and Congressional challenges, and legislative initiatives to modify, limit, or repeal the Affordable Care Act continue. It remains to be seen, however, precisely what new health care reform legislation will be enacted, if any, and what impact it will have on the availability of health care and containing or lowering the cost of health care. The manner in which the Affordable Care Act continues to evolve could materially affect the extent to which and the amount at which health care products and services are reimbursed by government programs such as Medicare, Medicaid and Tricare. We cannot predict all impacts the Affordable Care Act or other health care reform legislation may have on our products, but it may result in our products being chosen less frequently or the pricing being substantially lowered.

In addition, other health care reform proposals have emerged at the federal and state levels, including those aimed at reducing health care costs and increasing transparency. We cannot predict the effect these newly enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may lower reimbursements for our products, increase our compliance and other costs, and adversely affect our business.

We cannot predict what additional healthcare reform initiatives may be adopted in the future or how federal and state legislative and regulatory developments are likely to evolve, but we expect ongoing initiatives in the United States to increase pressure on pricing for health care products and services. Such reforms could have an adverse effect on the pricing and market for 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. During the summer of 2014, Israel was engaged in an armed conflict with Hamas in Gaza, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In addition, recent political uprisings and conflicts in various countries in the Middle East, including Egypt and Syria, are affecting the political stability of those countries. It is not clear how this instability will develop and how it will affect the political and security situation in the Middle East. This instability has raised concerns regarding security in the region and the potential for armed conflict. In addition, it is widely believed that Iran, which has previously threatened to attack Israel, has been stepping up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. Additionally, the Islamic State of Iraq and Levant ("ISIL"), a violent jihadist group, is involved in hostilities in Iraq and Syria. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy in general and us in particular. 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. 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.

Our operations may be disrupted as a result of the obligation of management or personnel to perform military service.

Many of our male employees in Israel, including members of our senior management, perform up to one month, and in some cases more, of annual military reserve duty until they reach the age of 45 or older and, in the event of a military conflict, may be called to active duty. There have also been periods of significant call-ups of military reservists, and it is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees. Such disruption could materially adversely affect our business, financial condition and results of operations.

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.

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

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

We timely requested a hearing before the Panel, which request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires. At the hearing, we will present its plan to evidence compliance with the minimum stockholders' equity requirement for continued listing on the NASDAQ Capital Market, and request an extension of time within which to do so. The hearing has been scheduled for May 2, 2019. If we do not receive a positive ruling on May 2, 2019, or if we fail to satisfy another NASDAQ requirement for continued listing, Staff could provide notice that our common stock will become subject to delisting.

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. 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.

Complying with the laws and regulations affecting public companies has increased and will increase our costs and the demands on management and could harm our operating results.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the Securities Exchange Commission and the NASDAQ Stock Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

For example, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. Section 404 of the Sarbanes-Oxley Act ("Section 404") requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404, including the requirement that our independent registered public accounting firm undertake an assessment of our internal control over financial reporting, will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the Securities Exchange Commission or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

If we fail to maintain effective internal control over financial reporting, the market price of our securities 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 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.

While we currently qualify as an "emerging growth company" under the Jumpstart of Business Startups Act of 2012, or the JOBS Act, we could lose that status, which may increase the costs and demands placed upon our management.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, and would continue to be an emerging growth company until December 31, 2022, or until the earliest of (i) the last day of the fiscal year during which we had total annual gross revenues of $1.07 billion (as indexed for inflation); (ii) the date on which we have, during the previous 3-year period, issued more than $1 billion in non-convertible debt; or (iii) the date on which we are deemed to be a 'large accelerated filer,' as defined by the Securities and Exchange Commission, which would generally occur upon our attaining a public float of at least $700 million. Once we lose emerging growth company status, we expect the costs and demands placed upon our management to increase, as we would have to comply with additional disclosure and accounting requirements, particularly if we would also no longer qualify as a smaller reporting company.

We are an "emerging growth company" and we cannot be certain that the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

The JOBS Act permits "emerging growth companies" like us to rely on some of the reduced disclosure requirements that are already available to smaller reporting companies. As long as we qualify as an emerging growth company or a smaller reporting company, we would be permitted to omit an auditor's attestation on internal control over financial reporting that would otherwise be required by the Sarbanes-Oxley Act, and are also exempt from the requirement to submit "say-on-pay", "say-on-pay frequency" and "say-on-parachute" votes to our stockholders and may avail ourselves of reduced executive compensation disclosure that is already available to smaller reporting companies.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this until we are no longer an emerging growth company or until we affirmatively and irrevocably opt out of this exemption. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will cease to be an emerging growth company at such time as described in the risk factor immediately above. Until such time, however, we cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and could cause our stock price to decline.

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. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of us the trading price for our securities would be negatively affected. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our securities and their trading volume to decline.

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We lease an office and manufacturing facility in Nesher, Israel and maintain an office in Tyler, Texas. Our lease for the facility in Nesher expires on June 30, 2020. The space is approximately 160 square meters. We pay approximately $3,600 per month under our lease. We also use a facility in Tyler, Texas from an unrelated party, for which we do not have a lease nor do we pay any rent. 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 litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

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

The last reported sale price for our common stock on the NASDAQ as of April 15, 2019 was $3.80 per share. As of April 15, 2019, we had 4,076,552 issued and outstanding shares of common stock, which were held by 121 holders of record.

As of April 15, 2019, we had a total of 2,733,142 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 15, 2019, we had a total of 304 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.

Recent Sales of Unregistered Securities

None

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

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

Recent Events

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

Holders of the warrants who entered into the amendment with the Company include the following affiliates of the Company: (i) a subsidiary of IDT Corporation, a greater than five percent stockholder of the Company, who holds warrants to purchase 266,667 shares of common stock at $3.35 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share, and (ii) entities controlled by Mr. Paul Packer and Mr. Packer, a greater than five percent stockholder of the Company, who holds warrants to purchase 66,666 shares of common stock at $3.35 per share and warrants to purchase 66,666 shares of common stock at $6.00 per share.

On February 20, 2019, we entered into a consulting agreement (the "Agreement") with Bespoke Growth Partners, Inc. ("Bespoke"), pursuant to which Bespoke will provide to us consulting services with respect to, among other things, advancement of our business plan, possible joint ventures, strategic alliances, mergers and acquisitions and related development activities (the "Services").

In consideration for the Services, we paid Bespoke a cash fee of $50,000 and issued to Bespoke 275,000 shares of our common stock upon signing the Agreement. In addition, if we have not previously terminated the Agreement, we agree to issue Bespoke (i) an additional 75,000 shares of our common stock on the three (3) month anniversary of the Agreement, (ii) an additional 200,000 shares of our common stock on the seven (7) month anniversary of the Agreement, and (iii) an additional 100,000 shares of our common stock on the ten (10) month anniversary of the Agreement. The Agreement contains a blocker provision that prohibits the issuance of our common stock to Bespoke during the term of the Agreement which would cause the beneficial ownership of Bespoke and its affiliates to exceed 9.99% of our outstanding shares of common stock.

The Agreement has an initial term of one year, unless we terminate earlier. Wemay terminate the Agreement before the end of the initial term upon 30 calendar days' notice to Bespoke. The Agreement provides for us to indemnify Bespoke, its officers, directors, members, employees, affiliates, and agents of all losses, expenses, damages and costs, including reasonable attorneys' fees, resulting from any act, action or omission, except for acts of Bespoke of willful misconduct, bad faith or gross negligence related to the Agreement.

NASDAQ Delisting Procedure

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

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

We timely requested a hearing before the Panel, which request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires. At the hearing, we will present its plan to evidence compliance with the minimum stockholders' equity requirement for continued listing on the NASDAQ Capital Market, and request an extension of time within which to do so. The hearing has been scheduled for May 2, 2019. If we do not receive a positive ruling on May 2, 2019, or if we fail to satisfy another NASDAQ requirement for continued listing, Staff could provide notice that our common stock will become subject to delisting.

Bridge Financing

On March 29,2019, we completed a bridge financing, pursuant to which we issued to two accredited investors convertible notes on the aggregate principal amount of $225,000 (the "Notes") and seven-year warrants (the "Warrant") to purchase an aggregate of 90,000 shares of our common stock or series C preferred stock at an exercise price of the *lesser* of: (a) 80% (*i.e*., a 20% discount) of the exercise price per share of the warrants to purchase shares of our capital stock issued in our first equity financing following the date of issuance, or (b) $4.80, with a stipulation that in no event will the exercise price be less than $3.00 per warrant share.

The principal amount and all accrued but unpaid interest on the Notes are due and payable on the date (the "Maturity Date") that is the earlier of the (i) 5-year anniversary of the date of issuance, or (ii) the date we complete an equity financing pursuant to which we issue and sell shares of capital stock resulting in aggregate proceeds of at least $2,000,000 (a "Qualified Financing"). The Notes bear interest at a rate of 6% per annum, payable on the Maturity Date.

To the extent not previously converted, on the Maturity Date, the investors will receive, at the option of each the investor, either (a) cash equal to the original principal amount of the Note and interest then accrued and unpaid thereon, or (b) shares of our common stock or our series C convertible preferred stock, at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company as of the Maturity Date, as determined in good faith by our board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, as of the Maturity Date on a fully diluted basis, and (y) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the capital stock of the Company.

Upon consummation of a Qualified Financing, each investor may elect to have the outstanding principal and accrued but unpaid interest thereon converted into (a) shares of the same class and series of equity securities sold in such Qualified Financing, (b) shares of series C convertible preferred stock or (c) common stock, at a price per share equal to the lesser of: (a) 80% of the price per share at which such securities are sold in such Qualified Financing and (b) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our capital stock.

In no event will the number of shares to be issued upon (i) exercise of this Warrants, (ii) conversion of the Notes exceed, in the aggregate, 9.9% of the total shares outstanding or the voting power outstanding on the date immediately preceding the date of issuance.

Critical Accounting Policies

Use of estimates

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

Functional currency

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

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

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

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

Revenue recognition

We generate revenues from the sale of our products to distributors and patients. Revenues from those products are recognized in accordance with ASC 606*Revenue from Contracts with Customers)*, in which its core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

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

Stock-based compensation

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

We have early adopted Accounting Standard Update ("ASU") 2016-09, "Compensation - Stock Compensation", in the 2016 consolidated financial statements and account for forfeitures as they occur.

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

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

Income taxes

Tax legislation from the Tax Cuts and Jobs Act ("Tax Reform Act") passed on December 22, 2017 was incorporated into the tax provision, making broad and complex changes to the U.S. tax code, including, but not limited to, (1) reducing the U.S. federal corporate tax rate from 35 percent to 21 percent: (2) requiring companies to pay a one-time transition tax on certain unrepatriated earnings of foreign subsidiaries: (3) generally eliminating U.S. federal income taxable income of certain earnings of controlled foreign corporations: (5) eliminating the corporate alternative minimum tax ("AMT") and changing how existing AMT credits can be realized: (6) creating the base erosion anti-abuse tax, a new minimum tax: (7) creating a new limitation on deductible interest expense: and (8) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017. The Tax Reform Act created new taxes on certain foreign-sourced earnings and certain related-party payments, which are referred to as the global intangible low-taxed income tax and the base erosion tax, respectively.

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.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes, related to balance sheet classification of deferred taxes. The ASU requires that deferred tax assets and liabilities be classified as noncurrent in the statement of financial position, thereby simplifying the current guidance that requires an entity to separate deferred assets and liabilities into current and noncurrent amounts. For public entities, this standard is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. For all other entities, this standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. We early adopted ASU 2015-17 as of December 31, 2017, which had no impact on our consolidated financial statements.

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

Warrants

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

Stock warrants are accounted for as a liability if they contain "down-round protection" or other terms that could potentially require "net cash settlement" in accordance with the provisions of ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity ("ASC 815"), which provides a two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock and thus able to qualify to be a derivative financial instrument. We measure such warrants at fair value by applying the Black-Scholes option pricing model in each reporting period until they are exercised or expired, with changes in the fair value being recognized in the our statement of operations as financial income or expense, as appropriate.

Debt Issued with Warrants

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

Recently issued accounting standards

For a summary of recent accounting pronouncements applicable to our consolidated financial statements see Note 2, "Significant Accounting Policies" to the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Extended Transition Period for "Emerging Growth Companies"

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the Jumpstart Our Business Act of 2012 (known as the JOBS Act). This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. Because our consolidated financial statements may not be comparable to companies that comply with public company effective dates, investors may have difficulty evaluating or comparing our business, performance or prospects in comparison to other public companies, which may have a negative impact on the value and liquidity of our common stock.

Going Concern

The financial statements have been prepared assuming that we will continue as a going concern. Our ability to continue to operate is dependent mainly on our ability to successfully market and sell our products and the receipt of additional financing until profitability is achieved. We have incurred losses in the amount of $4,154 during the year ended December 31, 2018, and have accumulated negative cash flow from operating activities amounted to $ 3,550 for the year ended December 31, 2018. We expect to continue incurring losses and negative flows from operations. As a result, we will not have sufficient resources to fund our operations for the next twelve months from the date of filing. These conditions raise substantial doubts about our ability to continue as a going concern. During the next twelve months management expects that we will need to raise additional capital to finance our 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. Management's plans include the continued commercialization of our products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products and raising capital, we will need to reduce activities, curtail or cease operations. The financial statements do not include any adjustments with respect to the carrying amounts of assets and liabilities and their classification that might be necessary should we be unable to continue as a going concern.

Results of Operations

Twelve Months Ended December 31, 2018 Compared to Twelve Months Ended December 31, 2017

Revenues. For the twelve months ended December 31, 2018 and 2017, our revenues were approximately $318,000 and $239,000, respectively, an increase of approximately 33%, or $79,000, between the periods. The increase was mainly attributable to increased sales from adding distributors. Our revenues may fluctuate as we add new customers or when existing distributors make large purchases of our products during one period and no purchases during another period. Our revenues by quarter may not be linear or consistent. We do not anticipate that our revenues will be impacted by inflation or changing prices in the foreseeable future.

For the twelve months ended December 31, 2018, the percentage of revenues attributable to our products was: PainShield – 73.9% and UroShield – 26.1%. For the twelve months ended December 31, 2017, the percentage of revenues attributable to our products was: PainShield – 75.7% and UroShield – 24.3%. For the twelve months ended December 31, 2018 and 2017, the percentage of revenues attributable to our disposable products was 33.1% and 47.4%, respectively. For the twelve months ended December 31, 2018 and 2017, the portion of our revenues that was derived from distributors was 55% and 47%, respectively.

Gross Profit. For the twelve months ended December 31, 2018, gross profit increased by approximately 5%, or $9,000, to approximately $160,000 from approximately $151,000 during the same period in 2017.

Gross profit as a percentage of revenues were approximately 50% and 63.2% for the twelve months ended December 31, 2018 and 2017, respectively. The decrease in gross profit as a percentage is mainly due to increased costs incurred in the process of moving the manufacturing process from our facilities to a third-party manufacturer which entailed among other costs a one-time $18,000 set-up fee, a one-time $41,000 price reduction awarded to a distributor which was recognized as a reduction to revenues, and to a lesser degree due to the increased sales to distributors which typically are sold at lower margins, as well as a lower percentage of sales of disposable products which contain a higher gross margin.

Our gross profit may be affected year-over-year by the mix of revenues between sales to distributers and sales directly to the end customers (where sales directly to the end customers generally have a higher margin). As a result, we are subject to year-over-year fluctuation in our gross profits.

Research and Development Expenses. For the twelve months ended December 31, 2018 and 2017, research and development expenses were $614,000 and $693,000, respectively, a decrease of approximately 11%, or $79,000, between the periods. This decrease was mainly due to decreased payroll expenses.

Research and development expenses as a percentage of total revenues were approximately 193% and 290% for the twelve months ended December 31, 2018 and 2017, respectively.

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

Selling and Marketing Expenses. For the twelve months ended December 31, 2018 and 2017, selling and marketing expenses were approximately $1,212,000 and $465,000, respectively, an increase of approximately 161%, or $747,000, between the periods.

The increase in selling and marketing expenses was mainly due to increased sales and marketing personnel, and to a lesser degree increased trade show expenses and marketing campaigns.

Selling and marketing expenses as a percentage of total revenues were approximately 381% and 195% for the twelve months ended December 31, 2018 and 2017, respectively. The increase in our percentage was due to the decreased spending mentioned above.

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

General and Administrative Expenses. For the twelve months ended December 31, 2018 and 2017, general and administrative expenses were approximately $2,637,000 and $2,084,000, respectively, an increase of approximately 27%, or $553,000, between the periods. The increase was mainly attributable to increased consulting and professional fees and to a smaller degree increased management compensation.

General and administrative expenses as a percentage of total revenues were approximately 829% and 872% for the twelve months ended December 31, 2018 and 2017, respectively. The decrease was due to the increase in revenues.

Our general and administrative expenses consist mainly of payroll expenses for management and administrative employees, costs associated with being a publicly traded company, stock-based compensation expenses, accounting and facilities expenses associated with general and administrative activities.

Financial Expenses, net. For the twelve months ended December 31, 2018 and 2017, financial expenses, net were $22,000 and $1,836,000, respectively, a decrease of approximately 99%, or $1,814,000, between the periods. The decrease resulted primarily from no longer recording a valuation adjustment of our warrants which were exercised in 2017.

Tax benefit (expenses). For the twelve months ended December 31, 2018, our tax benefit was approximately $127,000 and for the twelve months ended December 31, 2017 our tax expense was approximately $38,000. Our tax benefit for 2018 was derived from favorable adjustments due to lapses of statutes of limitations on its Israel tax positions. Our tax expense for 2017 is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate and unrecognized tax benefits as a result of tax positions taken.

Net Loss. Our net loss decreased by approximately $811,000, or 16%, to approximately $4,154,000 for the twelve months ended December 31, 2018 from approximately $4,965,000 during the same period in 2017. The decrease in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

We have incurred losses in the amount of $4,154,000 during the year ended December 31, 2018, and had negative cash flow from operating activities of $3,550,000 for the year ended December 31, 2018. We expect to continue to incur losses and negative cash flows from operating activities and as a result, we do not have sufficient resources to fund our operation for the next twelve months from the date of this filing. These conditions raise substantial doubts about our 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 for the next twelve months and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability.

During the year ended December 31, 2018, and through April 15, 2019, we met our short-term liquidity requirements from our existing cash reserves and from proceeds from the sales of convertible promissory notes in an aggregate amount of $1,380,000, as well as the net proceeds of $5,056,000 from our underwritten public offering of common stock and warrants which closed on November 6, 2017. 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. 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. We expect to continue to incurr losses and negative flows from operations. As a result, we will not have sufficient resources to fund our operations for the next twelve months. These conditions raise substantial doubt about our ability to continue as a going concern. During the next twelve months we expect that we will need to raise additional capital to finance our 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. Our plans include the continued commercialization of our products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that the we will be successful in obtaining the level of financing needed for our operations. If the we are unsuccessful in commercializing our products and raising capital, we will need to reduce activities, curtail or cease operations. It should also be noted that there are no assurances that we would be able to raise additional capital on terms favorable to us.

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. However, we may be unable to raise sufficient additional capital when we require it or upon terms favorable to us. In addition, the terms of any securities we issue in future financings may be more favorable to new investors and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding. If we are unable to obtain adequate funds on reasonable terms, we will need to curtail operations significantly, including possibly postponing anticipated clinical trials or entering into financing agreements with unattractive terms.

We do not have any material commitments to capital expenditures as of December 31, 2018, and we are not aware of any material trends in capital resources that would impact our business.

Twelve Months Ended December 31, 2018 Compared to Twelve Months Ended December 31, 2017

General. As of December 31, 2018, we had cash and cash equivalents of approximately $896,000, compared to approximately $4,360,000 as of December 31, 2017. We have historically met our cash needs through a combination of issuance of equity, borrowing activities and sales. Our cash requirements are generally for product development, research and development cost, marketing and sales activities, general and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately $3,550,000 for the twelve months ended December 31, 2018 and approximately $2,182,000 for the same period in 2017. The increase in our usage of cash in our operating activities in the amount of $1,368,000 is mainly attributable to the increase in costs associated the increase in selling expenses and, increased consulting fees, professional fees and management compensation.

Cash was used in our investing activities was approximately $8,000 during the twelve months ended December 31, 2018 compared to no investing activities during the twelve months ended December 31, 2017.

Cash provided by financing activities was approximately $94,000 from proceeds received on the exercise of warrants and option in 2018 compared to $6,436,000 received in 2017 from proceeds from the sales of the 2017 Notes in an aggregate amount of $1,380,000, as well as the net proceeds of $5,056,000 from our underwritten public offering which closed on November 6, 2017. Our future capital requirements and the adequacy of available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments.

Off Balance Sheet Arrangements

As of December 31, 2018, we have no off-balance sheet transactions, arrangements, obligations, or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. 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 SUPPLMENTARY 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.

Evaluation of Disclosure Controls and Procedures

Management is required to maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports, filed under the Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by the SEC Rules 13a-15(b) and 15d-15(b), an evaluation is required to be carried out under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses described below.

To address these material weaknesses, management engaged financial consultants, performed 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.

Management's Annual Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting ("ICFR") for the Company. Our internal control system was designed to, in general, provide reasonable assurance to the Company's management and board regarding the preparation and fair presentation of published financial statements, but 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 the policies or procedures may deteriorate.

As of December 31, 2018, management has not completed a proper evaluation, risk assessment and monitoring of the Company's internal controls over financial reporting based on the 2013 Committee of Sponsoring Organizations (COSO) framework. Management concluded that, during the period covered by this report, that our internal controls and procedures were not effective to detect the inappropriate application of US GAAP.

Based on our assessment, we concluded that we have control deficiencies in the design and operating effectiveness of our internal controls over financial reporting that aggregate to material weaknesses, individually and in the aggregate, as follows:

1. 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, we did not evaluate whether the providers were appropriately managing its and the Company's IT infrastructure, operations, and critical financial systems.

2. We did not maintain effective controls over managements review procedures including maintaining sufficient evidence of such review procedures for processing, recording and reviewing transactions related to certain contracts, accounting memos and certain monthly closing procedures.

3. We have not formalized and implemented a complete set of policy and procedure documentation to evidence or system of internal controls over financial reporting to meet the requirements of the COSO 2013 framework.

Management has also concluded that such weaknesses of its internal control did not have a material impact on our ability to fairly present our financial position, results of operations and cash flows for the years covered thereby in all material respects for the year ended December 31, 2018.

We will remediate these weaknesses described above, including by engaging a financial reporting advisor with expertise in accounting for complex transactions. We intend to continue to address these weaknesses as resources permit.

Notwithstanding the material weaknesses identified herein, we believe that our consolidated financial statements contained in this Annual Report fairly present our financial position, results of operations and cash flows for the years covered thereby in all material respects.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control over Financial Reporting.

There have been no changes in our internal control over financial reporting during the year ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 29, 2019, the Company completed a bridge financing, pursuant to which the Company issued to two accredited investors convertible notes on the aggregate principal amount of $225,000 (the "Notes") and seven-year warrants (the "Warrants") to purchase an aggregate of 90,000 shares of the Company's common stock or series C preferred stock at an exercise price of the *lesser* of: (a) 80% (*i.e.*, a 20% discount) of the exercise price per share of the warrants to purchase shares of the Company's capital stock issued in the first equity financing of the Company following the date of issuance, or (b) $4.80, with a stipulation that in no event will the exercise price of be less than $3.00 per warrant share.

The principal amount and all accrued but unpaid interest on the Notes are due and payable on the date (the "Maturity Date") that is the earlier of the (i) 5-year anniversary of the date of issuance, or (ii) the date the Company completes an equity financing pursuant to which the Company issues and sells shares of capital stock resulting in aggregate proceeds of at least $2,000,000 (a "Qualified Financing"). The Notes bear interest at a rate of 6% per annum, payable on the Maturity Date. To the extent not previously converted, on the Maturity Date, the investors will receive, at the option of each the investor, either (a) cash equal to the original principal amount of the Note and interest then accrued and unpaid thereon, or (b) shares of common stock or series C convertible preferred stock of the Company, at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company as of the Maturity Date, as determined in good faith by the Company's board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, as of the Maturity Date on a fully diluted basis, and (y) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the capital stock of the Company. Upon consummation of a Qualified Financing, each investor may elect to have the outstanding principal and accrued but unpaid interest thereon converted into (a) shares of the same class and series of equity securities sold in such Qualified Financing, (b) shares of series C convertible preferred stock or (c) common stock, at a price per share equal to the lesser of: (1) 80% of the price per share at which such securities are sold in such Qualified Financing and (2) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the Company's capital stock.

In no event will the number of shares to be issued upon (A) exercise of this Warrants and (B) conversion of the Notes exceed, in the aggregate, 9.9% of the total shares outstanding or the voting power outstanding on the date immediately preceding the date of issuance.

The foregoing descriptions of the Notes and the Warrants are not complete and are qualified in their entireties by reference to the full text of the Notes and the form of Warrant, copies of which are filed herewith as Exhibit 10.37, Exhibit 10.38 and Exhibit 10.39, respectively, to this Annual Report on Form 10-K and are incorporated by reference herein.

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 2018 annual meeting of stockholders, which shall be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K (the "Proxy Statement"), and is incorporated herein by reference.

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.

PART IV

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.

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 sheet of NanoVibronix,Inc (the "Company") as of December 31, 2018, the related consolidated statement of operations, stockholders' deficiency and cash flows for the year ended December 31, 2018, 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, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

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 1, the Company has a significant working capital deficiency, has incurred significant losses from operations 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 1. 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Marcum LLP

Marcum LLP

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

New York, NY
April 15, 2019

CONSOLIDATED BALANCE SHEETS

Amounts in thousands

	December 31,	
	2018	**2017**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 896	$ 4,360
Trade receivables	95	24
Inventories	144	76
Prepaid expenses and other accounts receivable	95	61
Total current assets	1,230	4,521
NON-CURRENT ASSETS:		
Property and equipment, net	8	6
Severance pay fund	342	338
Total non- current assets	354	344
Total assets	$ 1,580	$ 4,865

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

CONSOLIDATED BALANCE SHEETS

Amounts in thousands (except share and per share data)

	December 31,	
	2018	**2017**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Trade payables	$ 193	$ 168
Other accounts payables	447	629
Total current liabilities	640	797
NON- CURRENT LIABILITIES:		
Accrued severance pay	477	434
Total liabilities	1,117	1,231
COMMITMENTS AND CONTINGENT LIABILITIES		
STOCKHOLDERS' EQUITY (DEFICIENCY):		
Stock -		
Common stock of $ 0.001 par value - Authorized: 20,000,000 shares at December 31, 2018 and 2017; Issued and outstanding: 3,801,522 and 3,935,865 shares at December 31, 2018 and 2017, respectively	4	4
Series C Preferred stock of $ 0.001 par value - Authorized: 5,000,000 shares at December 31, 2018 and 2017; Issued and outstanding: 2, 733,142 and 2,483,142 at December 31, 2018 and 2017, respectively	2	2
Series D Preferred stock of $ 0.001 par value - Authorized: 5,000 and 5,000 shares at December 31, 2018 and 2017; Issued and outstanding: 304 at December 31, 2018 and 2017, respectively	*)	*)
Additional paid-in capital	32,993	32,010
Accumulated deficit	(32,536)	(28,382)
Total stockholders' equity (deficiency)	463	3,634
Total liabilities and stockholders' equity (deficiency)	$ 1,580	$ 4,865

*) Represents an amount lower than $ 1 thousands.

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

CONSOLIDATED STATEMENTS OF OPERATIONS

Amounts in thousands (except share and per share data)

	Year ended December 31,	
	2018	**2017**
Revenues	$ 318	$ 239
Cost of revenues	158	88
Gross profit	160	151
Operating expenses:		
Research and development	614	693
Selling and marketing	1,212	465
General and administrative	2,637	2,084
Total operating expenses	4,463	3,242
Operating loss	(4,303)	(3,091)
Financial expense, net (Note 12)	22	1,836
Loss before taxes on income	(4,281)	(4,927)
Tax Benefit (taxes) on income	127	(38)
Net Loss	$ (4,154)	$ (4,965)
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2017	—	841
Total loss attributable to holders of Common stock, Preferred C stock and Preferred D stock	$ (4,154)	$ (5,806)
Common stock, Preferred C stock and Preferred D stock basic and diluted net loss per share (Note 2q)	$ (0.64)	$ (1.17)
Weighted average number of shares of Common stock, Preferred C stock and Preferred D stock used in computing basic and diluted net loss per share (Note 2q)	6,448,343	4,964,077

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

Amounts in thousands (except share data)

	Preferred C stocks		Preferred D stocks		Common stocks		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficiency)
	Number	Amount	Number	Amount	Number	Amount			
Balance as of January 1, 2017	1,951,261	$ 2	—	—	2,632,710	$ 2	$ 20,073	$ (22,576)	$ (2,499)
Stock-based compensation related to options granted to employees	—	—	—	—	—	—	800	—	800
Issuance of warrants to Common stock	—	—	—	—	—	—	852	—	852
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2017	—	—	—	—	—	—	841	(841)	0
Proceeds from issuance of Common stock, Preferred D stock and warrants, net of issuance costs	—	—	327	—	897,958	1	5,055	—	5056
Conversion of convertible notes and accrued interest into Common and Preferred D stock	—	—	131	—	230,680	1	1,761	—	1,762
Conversion of Preferred D into Common stock	—	—	(154)	—	153,530	—	—	—	—
Issuance of Common and Preferred C stock upon cashless exercise of warrants and reclassification from liability to equity	531,881	—	—	—	20,987	—	2,628	—	2,628
Total loss	—	—	—	—	—	—	—	(4,965)	(4,965)
Balance as of December 31, 2017	2,483,142	$ 2	304	$ 0	3,935,865	$ 4	$ 32,010	$ (28,382)	$ 3,634
Stock-based compensation related to options granted to employees	—	—	—	—	—	—	889	—	889
Exercise of warrants for Common stock	—	—	—	—	67,670	—	91	—	91
Exercise of stock options for Common stock	—	—	—	—	48,017	—	3	—	3
Exchange of Common Stock into Preferred D	250,000	—	—	—	(250,000)	—	—	—	0
Total loss	—	—	—	—	—	—	—	(4,154)	(4,154)
Balance as of December 31, 2018	2,733,142	$ 2	304	$ 0	3,801,552	$ 4	$ 32,993	$ (32,536)	$ 463

*) Represents an amount lower than $1.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

Amounts in thousands

	Year ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (4,154)	$ (4,965)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6	5
Stock-based compensation	889	800
Discount amortization of promissory notes	—	1,197
Revaluation of warrants to purchase Common stock	—	549
Changes in operating assets and liabilities:		
Trade receivables	(71)	(18)
Prepaid expenses and other accounts receivable	(34)	(14)
Inventories	(68)	(9)
Trade payables	25	86
Other accounts payable	(182)	183
Accrued severance pay, net	43	4
Other assets	(4)	—
Net cash used in operating activities	(3,550)	(2,182)
Cash flows from investment activities:		
Purchase of property and equipment	(8)	—
Net cash used in investment activities	(8)	—
Cash flows from financing activities:		
Proceeds from issuance of Convertible Promissory Notes and warrants	—	1,380
Proceeds from issuance of Common stock, Preferred D stock and warrants, net of issuance costs	—	5,056
Proceeds from exercise of Warrants	91	—
Proceeds from exercise of options	3	—
Net cash provided by financing activities	94	6,436
Increase (decrease) in cash and cash equivalents	(3,466)	4,254
Cash and cash equivalents at the beginning of the year	4,360	106
Cash and cash equivalents at the end of the year	$ 896	$ 4,360
Supplemental information and disclosure of non-cash financing transactions:		
Carve out of warrants' fair value from Convertible Promissory Notes	$ —	$ 852
Conversion of convertible notes and accrued interest into Common and Preferred D stock	$ —	$ 1,762
Cashless exercise of warrants	$ —	$ 2,628

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

NOTE 1:- GENERAL

a. General:

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 also commenced operations in October 2003.

b. Going concern, liquidity and capital resources:

The Company's ability to continue to operate is dependent mainly on its ability to successfully market and sell its products and the receipt of additional financing until profitability is achieved. The Company has incurred losses in the amount of $4,154 during the year ended December 31, 2018, has an accumulated deficit of $32,536 as of December 31, 2018 and has negative cash flow from operating activities that amounted to $ 3,550 for the year ended December 31, 2018.

The Company expects to continue incurring losses and negative flows from operations. As a result, the Company will not have sufficient resources to fund its operations for the next twelve months. These conditions raise substantial doubts about the Company's ability to continue as a going concern for a period within the year after the issuance of these financial statements.

During the next twelve months management expects that 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 its products do not reach commercial profitability. Management's plans include the continued commercialization of the Company's products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and raising capital, it will need to reduce activities, curtail or cease operations. The financial statements do not include any adjustments with respect to the carrying amounts of assets and liabilities and their classification that might be necessary should the Company be unable to continue as a going concern.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

a. 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's management 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

b. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, NanoVibronix (Israel 2003) Ltd. All intercompany balances and transactions have been eliminated upon consolidation.

c. Foreign currency translation and transaction

Non-U.S. dollar denominated transactions and balances have been re-measured to U.S. dollars. All transaction 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 financial income or expenses, as appropriate.

d. Cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at acquisition.

e. Inventories:

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.

f. 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

g. Impairment of long-lived assets:

The Company’s long-lived assets are reviewed for impairment in accordance with Accounting Standard Codification (“ASC”) 360, “Property, Plant, and Equipment”, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During the years ended December 31, 2018 and 2017, no impairment losses have been identified.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

i. 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.

Severance expenses for the years ended December 31, 2018 and 2017 amounted to $ 46 and $ 85, respectively.

j. Warrants:

The Company accounts for stock warrants held by investors as either equity instruments or liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), depending on the specific terms of the warrant agreement.

Stock warrants are accounted for as a liability if they contain "down-round protection" or other terms that could potentially require "net cash settlement" in accordance with the provisions of ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASC 815"), which provides a two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock and thus able to qualify to be a derivative financial instrument. The Company measures such warrants at fair value by applying the Black-Scholes option pricing model in each reporting period until they are exercised or expired, with changes in the fair value being recognized in the Company's statement of comprehensive loss as financial income or expense, as appropriate.

k. Debt Issued with Warrants:

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

The Company applied ASC 470-20 and ASC 815 to the Convertible promissory notes (see Note 7).

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

l. Revenue recognition:

The Company generates revenues from the sale of its products to distributors and patients. For the year ended December 31, 2018, revenues from those products are recognized in accordance with ASC 606 , *Revenue from Contracts with Customers,* whose core principle is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services.

During the year ending December 31, 2017, revenues were recognized in accordance with ASC 605, "Revenue Recognition," when delivery has occurred, persuasive evidence of an agreement exists, the fee is fixed or determinable, no further obligation exists and collectability is probable.

Revenues from sales to distributors are recognized at the time the products are shipped 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.

m. Research and development costs:

Research and development costs are charged to the statement of operations, as incurred.

n. 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.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes, related to balance sheet classification of deferred taxes. The ASU requires that deferred tax assets and liabilities be classified as noncurrent in the statement of financial position, thereby simplifying the current guidance that requires an entity to separate deferred assets and liabilities into current and noncurrent amounts. ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2017 and interim periods within those annual periods. ASU 2015-17 was adopted by the Company as of January 1, 2018, and had no impact on its consolidated financial statements.

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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

o. Stock-based payments:

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

The Company has early adopted ASU 2017-09 in the 2017 consolidated financial statements using a modified retrospective transition method by means of a cumulative-effect adjustment to equity as of the beginning of the period in which the guidance is adopted. As a result of this adoption, the Company recorded an increase to accumulated deficit of $11 resulting from the election of accounting policy to account for forfeitures as they occur as of January 1, 2017.

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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

p. Fair value of financial instruments:

ASC 820, "Fair Value Measurements and Disclosures," defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The hierarchy is broken down into three levels based on the inputs as follows:

Level 1 - Valuations based on quoted prices (unadjusted) in active markets for identical assets that the Company has the ability to access at the measurement date.

Level 2 - Valuations based on one or more quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The carrying amounts of cash and cash equivalents, trade receivables, prepaid expenses and other accounts receivable, trade payables and other accounts payables approximate their fair value due to the short-term maturities of such instruments.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

q. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of shares of Common stock, Preferred C and Preferred D stock outstanding during each year. Diluted net loss per share is computed based on the weighted average number of shares of Common stock, Preferred C and Preferred D stock outstanding during each year plus dilutive potential equivalent shares of Common stock, Preferred C and Preferred D stock considered outstanding during the year, in accordance with ASC 260, "Earnings per Share."

For the years ended December 31, 2018 and 2017, all outstanding stock options and warrants have been excluded from the calculation of the diluted net loss per share as all such securities are anti-dilutive for all years presented.

r. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. Cash and cash equivalents are invested in major banks in U.S. and Israel. Management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, minimal credit risk exists with respect to these investments.

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

s. Impact of recently issued accounting standards:

In May 2014, the Financial Accounting Standards Board (FASB), issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (ASC 606),* to supersede nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The Company has early adopted the new revenue standard as of January 1, 2018, using a modified retrospective adoption transition to each prior reporting period presented. The adoption did not have an effect on the Consolidated Financial Statements on the adoption date.

Revenue Recognition
Generally the Company considers all revenues as arising from contracts with customers. Revenue is recognized based on the five step process outlined in ASC606:

Step 1 – Identify the Contract with the Customer – A contract exists when (a) the parties to the contract have approved the contract and are committed to perform their respective obligations, (b) the entity can identify each party's rights regarding the goods or services to be transferred, (c) the entity can identify the payment terms for the goods or services to be transferred, (d) the contract has commercial substance and (e) it is probably that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Step 2 – Identify Performance Obligations in the Contract – Upon execution of a contract, the Company identifies as performance obligations each promise to transfer to the customer either (a) goods or services that are distinct or (b) a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer. To the extent a contract includes multiple promised goods or services, the Company must apply judgement to determine whether the goods or services are capable of being distinct within the context of the contract. If these criteria are not met, the goods or services are accounted for as a combined performance obligation.

Step 3 – Determine the Transaction Price – When (or as) a performance obligation is satisfied, the Company shall recognize as revenue the amount of the transaction price that is allocated to the performance obligation. The contract terms are used to determine the transaction price. Generally, all contracts include fixed consideration. If a contract did include variable consideration, the Company would determine the amount of variable consideration that should be included in the transaction price based on expected value method. Variable consideration would be included in the transaction price, if in the Company's judgement, it is probable that a significant future reversal of cumulative revenue under the contract would not occur.

Step 4 – Allocate the Transaction Price – After the transaction price has been determined, the next step is to allocate the transaction price to each performance obligation in the contract. If the contract only has one performance obligation, the entire transaction price will be applied to that obligation. If the contract has multiple performance obligations, the transaction price is allocated to the performance obligations based on the relative standalone selling price (SSP) at contract inception.

Step 5 – Satisfaction of the Performance Obligations (and Recognize Revenue)– When an asset is transferred and the customer obtains control of the asset (or the services are rendered), the Company recognizes revenue. At contract inception, the Company determines if each performance obligation is satisfied at a point in time or over time. For device sales, revenue is recognized at a point in time when the goods are transferred to the customer and they obtain control of the asset. For maintenance contracts, revenue is recognized over time as the performance obligations in the contracts are completed.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Product sales

The Company sells its products through distributors and directly to patients. Under ASC 606, revenue from product sales is recognized at the point in time when the shipment is made and when title and risk of loss transfers to these customers. Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration for customer rights of return using an expected value method. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Product sales are recorded net of estimated product returns and other deductions. The Company's adoption of ASC 606 did not have a material impact on the Company's financial statement.

Recently issued accounting standards

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted for all public business entities and all nonpublic business entities upon issuance. We are currently continuing to evaluate the impact of our pending adoption of ASU 2016-02 on our consolidated financial statements

In May 2017 the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU No. 2017-09 is effective for financial statements issued for annual reporting periods beginning after December 15, 2017 and interim periods within those years. Earlier application was permitted. The adoption of the new requirements of ASU No. 2017-09 did not have a material impact on the Company's consolidated financial position or results of operations

Amounts in thousands (except share and per share data)

NOTE 3:- PREPAID EXPENSES AND OTHER RECEIVABLES

	December 31,	
	2018	2017
Prepaid expenses	$ 42	$ 45
Other accounts receivable	49	11
	$ 91	$ 56

NOTE 4:- INVENTORIES

	December 31,	
	2018	2017
Raw materials	$ 110	$ 68
Work in process	13	-
Finished goods	21	8
	$ 144	$ 76

Amounts in thousands (except share and per share data)

NOTE 5:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2018	**2017**
Cost:		
Computers and peripheral equipment	$ 55	$ 47
Office furniture and equipment	3	3
	58	50
Accumulated depreciation:		
Computers and peripheral equipment	48	42
Office furniture and equipment	2	3
	(50)	(45)
Depreciated cost	$ 8	$ 5

Depreciation expenses for the years ended December 31, 2018 and 2017 were $6 and $7, respectively.

NOTE 6:- OTHER ACCOUNTS PAYABLE

	December 31,	
	2018	**2017**
Employees and payroll accruals	$ 204	$ 219
Accrued expenses	123	150
Income tax accrual	120	260
	$ 447	$ 629

NOTE 7:- CONVERTIBLE PROMISSORY NOTES

Since March 1, 2017 through September 30, 2017, the Company completed a series of bridge financings pursuant to which the Company has received from accredited investors $1,380 of loans and issued to the investors convertible promissory notes (the "2017 Notes") in the aggregate principal amount of $1,380, and seven-year warrants (the "Warrants") to purchase an aggregate of 552,000 shares of common stock at an exercise price of $5.90 per share.

The 2017 Notes accrued interest at a rate of 6% per annum, payable on the earlier of a 5-year anniversary of the issuance date, or the date that the Company completes a Qualified Financing, as defined in the agreement (the "Maturity Date"). To the extent not previously converted, on the Maturity Date, each investor had the right to receive, at the option of the investor, either (a) cash equal to the original principal amount of the 2017 Notes and interest then accrued and unpaid thereon, or (b) shares of common stock or Series C Convertible Preferred Stock of the Company, at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company as of the Maturity Date, as determined in good faith by the Company's board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, as of the Maturity Date on a fully diluted basis, and (y) $5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the capital stock of the Company. Upon consummation of a Qualified Financing, the investors may elect to have the outstanding principal and accrued but unpaid interest thereon converted into shares of the same class and series of equity securities sold in such Qualified Financing, provided that the investor may elect to receive shares of Series C Convertible Preferred Stock instead of shares of common stock, to the extent that common stock are issued in such Qualified Financing, at a price per share equal to the lesser of: (a) 80% of the price per share at which such securities are sold in such Qualified Financing and (b) $5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the Company's capital stock.

As a result of issuing the warrants and as a result of the discount on the conversion price of the 2017 Notes, the Company amortized the embedded benefit in the amount of $1,197 in the year ended December 31, 2017.

In September 2017, all of the holders of the 2017 Notes agreed to convert the full principal and accrued interest on the 2017 Notes into equity securities of the Company in the event the Company consummated a Qualified Financing anytime before December 31, 2017.

On November 6, 2017, the Company completed a public offering, which constituted a Qualified Financing, upon which the 2017 Notes were automatically converted. Based on the outstanding principal amount and all accrued but unpaid interest on the 2017 Notes, at 80% of the offering price of $4.90 per share of common stock and accompanying warrant, the Company issued an aggregate of 361,462 shares of common stock (and common stock equivalents) and warrants to purchase an aggregate of 271,096 shares of common stock to the holders of the 2017 Notes, all of which are subject to lock-up agreements for 180 days from November 1, 2017.

Amounts in thousands (except share and per share data)

NOTE 8:- COMMITMENTS AND CONTINGENT LIABILITIES

a. The Company leases office facilities and motor vehicles under operating leases, which expire on various dates, the latest of which is 2020.

Year ended December 31,	Operating leases
2019	$ 43
2020	$ 29
Total	$ 72

The Company leases motor vehicles under cancelable lease agreements. The Company has an option to be released from this lease agreement, which may result in penalties in a maximum amount of approximately $5.

Rent and related expenses were $31 and $27 for the years ended December 31, 2018 and 2017, respectively.

Motor vehicle leases, and related expenses were $42 and $15 for the years ended December 31, 2018 and 2017, respectively.

b. Royalties to the Israel Innovation Authority (“the IIA”):

Under the Company’s subsidiary research and development agreements with the IIA and pursuant to applicable laws, the Company is required to pay royalties at the rate of 3-3.5% of sales of products developed with funds provided by the IIA, up to an amount equal to 100% of the IIA research and development grants received, linked to the dollar including accrued interest at the LIBOR rate. The Company has received through the years grants in the amount of $ 437. The Company is obligated to repay the Israeli Government for the grants received only to the extent that there are sales of the funded products. As of December 31, 2018, there are no sales from the funded projects.

As of December 31, 2018, the Company has a contingent obligation to pay royalties in the principal amount of approximately $ 470. In addition, the IIA may impose certain conditions on any arrangement under which it permits the Company to transfer technology or development out of Israel.

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY)

a. 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.

b. Series C Preferred Stock:

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

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

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

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

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

c. Series D Preferred Stock:

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

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

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

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

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

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

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

Since the Company has sufficient authorized and unissued shares available to settle its commitments and since all holders of equally (both preferred stock and common stock) would receive the same form of consideration upon the consummation of a Fundamental Transaction, and the shares are not otherwise redeemable, the shares of Series D Preferred Stock are classified within permanent equity, consistent with the guidance of ASC 480.

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

d. In April 2017, the Company issued 9,000 restricted shares of Common stock to a consultant as part of the total consideration for its services associated with the Company's investor relation services. The restricted shares were fully vested during the year ended December 31, 2017. The stock based expense recognized in the financial statements for services received from the consultant in the year ended December 31, 2017 amounted to $49.

e. On October 4, 2017, the Company issued 358,995 shares of Series C Preferred stock, to the holders of certain warrants to purchase an aggregate of 563,910 shares of common stock that contained full ratchet anti-dilution price protection in such warrants pursuant to a cashless exercise of such warrants.

f. On November 2, 2017, the Company issued 20,987 shares of common stock and 172,886 shares of Series C Preferred Stock to the holders of certain warrants to purchase an aggregate of 299,733 shares of common stock pursuant to a cashless exercise of such warrants.

g. On November 6, 2017, the Company closed the Offering of 897,958 shares of the Company's common stock, 327 shares of the Company's Series D Preferred shares of the Company's common stock (and common stock equivalents) at an offering price of $4.90 per share of common stock, and $0.049 per share of Series D Preferred stock, and accompanying warrant to purchase 0.75 of one share of common stock. Total gross proceeds from the offering totaled approximately $6,000, and net proceeds of approximately $5,056 after deducting underwriting and estimated offering expenses. Each warrant has an exercise price of $6.95 per full share of common stock with a life term of five years. The securities were issued pursuant to the Company's registration statement on Form S-1 originally filed with the Securities and Exchange Commission on June 21, 2017, and declared effective on November 1, 2017.

h. Starting from March 1, 2017 through September 30, 2017, the Company completed a series of bridge financings pursuant to which the Company have received from accredited investors aggregate proceeds of $1,380 in exchange for 2017 Notes in the aggregate principal amount of $1,380, and seven-year Warrants to purchase an aggregate of 552,000 shares of common stock at an exercise price of $5.90 per share. Upon closing of the Offering, the 2017 Notes were automatically converted and as a result the Company issued an aggregate of 230,680 shares of common stock (and common stock equivalents), 131 shares of the Company's Series D preferred stock and warrants to purchase an aggregate of 271,096 shares of common stock.

Amounts in thousands (except share and per share data)

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

i. Warrants issued to investors:

The following table below summarizes the outstanding warrants issued to investors as of December 31, 2018 and 2017, respectively:

	Warrants outstanding as of December 31,			
	2018	2017	Exercise price $	Expiration date
November 2011 Warrants (1) (2)	—	245,893	1.393	November 15, 2018
February 2015 Warrants (3)	686,667	686,667	3.00/6.00	February 30, 2019
March through September 2017 Warrants (5)	552,000	552,000	5.90	May through September 2022
November 2017 Warrants (6)	1,296,605	1,250,687	6.90	November 1, 2022
Total outstanding	2,535,272	2,735,427		

1. In November 2011, the Company issued to some of its stockholders warrants to purchase 2,319,062 shares of Series B-2 Preferred stock with a fixed exercise price of $ 0.199 per share (reflecting a 30% discount on the fair value of the Company's Preferred stock on that date). The warrants expire on November 15, 2018. On May 2014, the Company effected a reverse split of the Company's stock of seven to one. In addition, on April 2015 all of the Company's B-2 warrants were reclassified as warrants to common shares. As a result, these warrants have a fixed exercise price of $1.393 to purchase 331,293 shares of Common Stock. During 2017, 85,400 of the Company's B-2 Warrants were exercised. During 2018, an additional 68,799 B-2 Warrants were exercised and the remaining 177,094 B-2 Warrants expired.

2. In February 2013 through December 2014, the Company issued to some of its stockholders warrants to purchase 563,910 shares of Common stock. The exercise price at which the warrant may be exercised is $ 2.66 per share, subject to adjustment for stock splits, fundamental transactions or similar events. The warrants were to expire in February 2018 through December 2019, based on the issuance date (see also Note 8a). On October 4, 2017, these warrants were cashless exercised (see also Note 10e).

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

3. In February 2015, the Company negotiated a securities purchase agreement which included warrants to purchase 840,000 shares of Common stock. The exercise price at which the warrant may be exercised is $3 for 420,000 shares and $6 for 420,000 shares, subject to certain adjustments. The warrants to purchase the 840,000 shares were to expire by February 2017. However, in January 2017, the Company agreed to extend the warrants to purchase the 840,000 shares by additional two years until February 2019 pursuant to the Warrant Amendment. On November 2, 2017, 153,333 of such warrants were cashless exercised (see also Note 10f).

4. On March 25, 2015, the Company issued warrants to purchase up to 61,000 shares of Common stock to a consultant as consideration for the provision of guidance and assistance in connection with the filing of the Company's Form 10 and becoming a public reporting company. The warrants had an exercise price of $2.57 per share, subject to adjustment for stock splits, fundamental transactions or similar events and were scheduled to expire on March 25, 2020. On November 2, 2017, these warrants were cashless exercised (see also Note 10f).

5. During the period March 1, 2017 through September 30, 2017, the Company completed a series of bridge financings pursuant to which the Company have received from accredited investors aggregate proceeds of $1,380 in exchange for 2017 Notes in the aggregate principal amount of $1,380, and seven-year Warrants to purchase an aggregate of 552,000 shares of common stock at an exercise price of $5.90 per share.

6. In conjunction with the Company's Offering for the issuance of 1,224,488 shares of the Company's Common stock, the Company also issued warrants to purchase up to 918,366 shares of common stock. Additionally, the Company issued to the underwriters a unit purchase option to purchase units at an exercise price equal to $6.125 pursuant to which an aggregate of 61,224 shares and warrants to purchase 45,918 shares are issuable to the underwriters. Upon closing of the Offering, the 2017 Notes were automatically converted and as a result the Company issued an aggregate of 361,462 shares of common stock (and common stock equivalents) and warrants to purchase an aggregate of 271,096 shares of common stock. The warrants have an exercise price of $6.90 per share, subject to adjustment for stock splits, fundamental transactions or similar events and shall expire on November 1, 2022.

j. Stock option plan:

In November 2004, the Board of Directors of the Company adopted a stock option plan ("the Plan"), according to which options may be granted to employees, directors and consultants.

Pursuant to the Plan, the Company reserved for issuance 400,000 shares of Common stock. Each option entitles the holder to purchase one share of Common stock of the Company and expires after 10 years from the date of grant. Any options that are terminated, cancelled, forfeited or not exercised, become available for future grants.

Amounts in thousands (except share and per share data)

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

In February 2014, the Board of Directors of the Company adopted a new stock option plan ("the New Plan"), according to which options may be granted to employees, directors and consultants.

Pursuant to the New Plan, the Company reserved for issuance 714,286 shares of Common stock. Each option entitles the holder to purchase one share of Common stock of the Company and expires after 10 years from the date of grant. Any options that are terminated, cancelled, forfeited or not exercised, become available for future grants.

On June 13, 2018 the Company's shareholders amended the NanoVibronix 2014 Long-Term Incentive Plan (the "2014 Plan"), to increase the aggregate number of shares of common stock reserved for issuance under the 2014 Plan by an additional 750,000 shares, to a total of 1,464,286 shares (the "Plan Amendment Proposal").

As of December 31, 2018, under the New Plan, 292,737 options were available for future grants.

In addition, the Company issued options to purchase 275,038 shares of Common Stock outside of the New Plan.

1. Option issued to employees, consutants and directors

A summary of the Company's options activity and related information with respect to options granted to employees, consultants, and directors during the years ended December 31, 2018 and 2017 are as follows:

	Number of options		Weighted average exercise price	Weighted average remaining contractual life	Aggregate intrinsic value
Outstanding - January 1, 2017	1,234,934	$	3.01	7.18	3,419
2017 Activity:					
Granted	—	$	—	—	—
Exercised	—	$	—	—	—
Expired or Forfeited	(7,160)	$	10.08	—	—
Outstanding - December 31, 2017	1,227,774	$	3.01	7.18	3,419
2018 Activity:					
Granted	338,750	$	4.75	9.65	735
Exercised	(48,017)	$	0.07	4.24	—
Expired or Forfeited	(71,920)	$	4.41	7.16	—
Outstanding - December 31, 2018	1,446,587	$	3.16	7.87	4,578
Exercisable at end of year - December 31, 2018	1,217,818	$	3.26	7.09	3,969

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

Weighted average fair value of options granted to employees and directors during the years 2018 and 2017 was $ 2.17 and $ 0 per option, respectively.

Aggregate intrinsic value of unexercised options by employees and directors during the years 2018 and 2017 was $ 0. The Aggregate intrinsic value of the unexercised options represents the total intrinsic value (the difference between the exercise price and fair value at the time of measurement) multiplied by the number of options exercised.

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing share price on the last trading day of calendar 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2018. This amount is impacted by the changes in the fair market value of the Company's shares.

As of December 31, 2018, the total unrecognized estimated compensation cost related to non-vested options granted prior to that date was $ 228 which is expected to be recognized over a weighted average period of approximately 2 years.

Amounts in thousands (except share and per share data)

NOTE 9:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

3. Total stock-based compensation:

The fair value for options granted in 2018 is estimated at the date of grant using a Black-Scholes-Merton options pricing model with the following underlying assumptions:

	Year ended December 31,	
	2018	**2017**
Risk free interest	2.77%	—
Dividend yields	0%	—
Volatility	54%	—
Expected term (in years)	5	—

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

The total stock based expense recognized in the financial statements for services received from employees and non-employees is shown in the following table (refer also to Note 10d):

	Year ended December 31,	
	2018	**2017**
Research and development	$ —	$ 30
Selling and marketing	16	13
General and administrative	873	757
Total	$ 889	$ 800

NOTE 10:- TAXES ON INCOME

a. As of December 31, 2018, the U.S. Company had federal and state net operating loss carry forward for tax purposes of approximately $ 17,838. $3,441 of the federal net operating loss can be carried forward indefinitely and 14,397 of the federal net operating losscan be offset against taxable income 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 provisions of the Internal Revenue Code of 1986.

b. U.S. Tax Cuts and Jobs Acts:

On December 22, 2017, the U.S. Tax Cuts and Jobs Acts was enacted into law. The new legislation contains several key tax provisions that will impact the Company. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, a one-time repatriation tax on accumulated foreign earnings, a limitation on the tax deductibility of interest expense, an acceleration of business asset expensing, and a reduction in the amount of executive pay that could qualify as a tax deduction. The lower corporate income tax rate will require the Company to remeasure its U.S. deferred tax assets as well as reassess the realizability of its deferred tax assets. ASC 740 requires the Company to recognize the effect of the tax law changes in the period of enactment. However, the SEC staff has issued SAB 118 which allowed the Company to record provisional amounts during a measurement period.

The Company has concluded that a reasonable estimate could be developed for the effects of the tax reform. These effects, which had an immaterial effect on the taxes on income due to the valuation allowance, have been included in the consolidated financial statements for the year ended December 31, 2018.

Amounts in thousands (except share and per share data)

NOTE 10:- TAXES ON INCOME (Cont.)

c. Foreign tax:

1. Tax rates applicable to the income of the Israeli subsidiary:

The Israeli corporate tax rate in 2018 and 2017 is 23% and 24%, respectively.

In December 2017, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2018 and 2017 Budget Years), 2017 which reduced the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

2. The subsidiary has final tax assessments through 2012.

d. Loss before taxes on income:

	Year ended December 31,	
	2018	**2017**
Domestic	$ 3,503	$ 4,930
Foreign	779	(3)
	$ 4,282	$ 4,927

e. 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:

	December 31,	
	2018	**2017**
Deferred tax assets:		
Net operating loss carry forward	$ 3,746	$ 2,722
Temporary differences	35	35
Deferred tax assets before valuation allowance	3,781	2,757
Valuation allowance	(3,781)	(2,757)
Net deferred tax asset	$ —	$ —

For the year ended December 31, 2018, the net change in valuation allowance of $1,024 was related to the increase in valuation allowance included in the income tax provision. For the year ended December 31, 2017, the decrease in valuation allowance of $1,171 was related to the change in valuation allowance due to a $1,571 reduction due to reduced benefits from the reduction of the corporate tax rates from 35% to 21% offset by an $400 increase in valuation allowance included in the income tax provision.

Amounts in thousands (except share and per share data)

NOTE 10:- TAXES ON INCOME (Cont.)

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 utilized. Based on consideration of these factors, the Company recorded a full valuation allowance at December 31, 2018 and 2017.

f. 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.

g. A reconciliation of the beginning and ending balances of uncertain tax benefits is as follows:

	December 31,	
	2018	**2017**
Balance at beginning of the year	$ 168	$ 170
Increases related to tax positions from prior years	—	17
Lapses of statutes of limitation	(168)	(19)
Balance at the end of the year	$ —	$ 168

The Company recognizes interest and penalties related to unrecognized tax benefits in tax expense. During the year ended December 31, 2018, the Company accrued $0 for interest and penalties expenses related to uncertain tax positions.

Amounts in thousands (except share and per share data)

NOTE 11:- FINANCIAL INCOME (EXPENSE), NET

	Year ended December 31,	
	2018	**2017**
Interest on promissory notes	$ —	$ (37)
Discount amortization of promissory notes	—	(1,197)
Change in fair value of warrants	—	(549)
Other financial income (expense)	22	(53)
	$ 22	$ (1,836)

NOTE 12:- GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

Summary information about geographic areas:

ASC 280, “Segment Reporting,” establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company manages its business on the basis of one reportable segment, and derives revenues from selling its products mainly through distributor agreements. The following is a summary of revenues within geographic areas:

	Year ended December 31,	
	2018	**2017**
United States	$ 164	$ 90
Israel	49	8
United Kingdom	50	74
European Union (excluding United Kingdom)	8	14
India	17	14
Other	30	39
	$ 318	$ 239

During the year ended December 31, 2018, there were sales to two distributors each of which accounted for approximately 22% of total sales. During the year ended December 31, 2017, there were sales to two distributors each of which accounted for approximately 11% of total sales.
The Company’s long-lived assets are all located in Israel.

NOTE 13:- RELATED PARTIES BALANCES AND TRANSACTIONS

Financial expenses – related part convertible note:

During the period ended December 31, 2017, the Company incurred $549 in financial expenses associated with the issuance of convertible notes to related party lenders (Refer to footnote 7 for more information).

Exchange of common stock for Preferred C stock:

In 2018, the Company exchanged 250,000 shares of common stock for 250,000 shares of Preferred C stock with a significant shareholder. The significant shareholder has the right to exchange an additional 50,000 common shares at their discretion.

Board members resignation and severance agreement:

On July 4, 2018, Jona Zumeris, Vice President of Technology and member of the board of directors of NanoVibronix, Inc. and the Company's subsidiary, submitted his resignation.

On July 4, 2018, the Company and Dr. Zumeris and his wife, Janina (Ina) Zumeris entered into a Separation and Release Agreement (the "Separation Agreement"), providing that Dr. Zumeris shall resign from all positions at the Company and that Dr. Zumeris and Janina Zumeris will cooperate with the Company and its officers on meeting certain technical and administrative milestones during the transition period ending 60 days following the date of the Separation Agreement (the "Termination Date"). If Dr. Zumeris and Janina Zumeris have met such milestones to the satisfaction of the Company and fulfilled other obligations under the Separation Agreement, (i) Dr. Zumeris and Janina Zumeris, will be entitled to receive as consulting payments an aggregate of approximately $18,000 per month for 12 months, commencing 30 days after the Termination Date; (ii) the Company's management, beginning on November 4, 2018, will use its best efforts to allow the sale of the Company's securities owned by Dr. Zumeris, provided that such sale would be in compliance with the applicable U.S. securities laws and regulations, and provided further, that, if the Company's shares of common stock held by Dr. Zumeris had not been sold at a price lower than $4.45 during the fourteen month period from July 4, 2018, and the value of the unsold securities Dr. Zumeris owns plus the value of cash received by Dr. Zumeris from the sale of the Company's securities during such fourteen month period (the "Aggregate Amount"), in aggregate, is less than $950,000, then the Company will make up the difference between $950,000 and the Aggregate Amount by extending the term of engagement of Dr. Zumeris and Janina Zumeris's consulting services. In addition, if the Company (i) grants a license for the skin rejuvenation technology, then the Company will pay Dr. Zumeris 10% from the payments received by the Company until an aggregate amount of $100,000 has been paid to Dr. Zumeris, (ii) sells the skin rejuvenation technology and/or the rights to such as a standalone product, the Company will pay Dr. Zumeris $100,000 from the proceeds of such sale, or (iii) sells the skin rejuvenation devices, the Company will pay Dr. Zumeris $5 per unit an aggregate amount of $100,000 has been paid to Dr. Zumeris.

U.S. dollars in thousands (except share and per share data)

NOTE 13:- RELATED PARTIES BALANCES AND TRANSACTIONS (Cont.)

In connection with the Company's agreement with Dr. Zumeris, the Company was to evaluate if any liability should be accrued for each reporting period. As of December 31, 2018, Dr. Zumeris exercised options under $4.45 a share and therefore the Company will not need to record a liability for this transaction.

During the year ended December 31, 2018, The Company incurred expenses of $108 associated with this agreement.

NOTE 14:- LOSS PER SHARE

All outstanding share options and warrants for the year ended December 31, 2018 and 2017 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, 2018	December 31, 2017
Series D Preferred Shares	303,782	303,782
Stock Options – employee and non-employee	734,756	812,773
Warrants	266,667	512,560
Total	1,305,205	1,629,115

NOTE 15: SUBSEQUENT EVENTS

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

Holders of the warrants who entered into the amendment with the Company include the following affiliates of the Company: (i) a subsidiary of IDT Corporation, a greater than five percent stockholder of the Company, who holds warrants to purchase 266,667 shares of common stock at $3.35 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share, and (ii) entities controlled by Mr. Paul Packer and Mr. Packer, a greater than five percent stockholder of the Company, who holds warrants to purchase 66,666 shares of common stock at $3.35 per share and warrants to purchase 66,666 shares of common stock at $6.00 per share.

NOTE 15: SUBSEQUENT EVENTS (Cont.)

On February 21, 2019, the Company entered into a consulting agreement (the "Agreement") with Bespoke Growth Partners, Inc. ("Bespoke"), pursuant to which Bespoke will provide the Company with consulting services with respect to, among other things, advancement of the Company's business plan, possible joint ventures, strategic alliances, mergers and acquisitions and related development activities (the "Services").

In consideration for the Services, the Company paid Bespoke a cash fee of $50,000 and issued to Bespoke 275,000 shares of the Company's common stock upon signing the Agreement. In addition, if the Company has not previously terminated the Agreement, the Company has agreed to issue Bespoke (i) an additional 75,000 shares of common ctock on the three (3) month anniversary of the Agreement, (ii) an additional 200,000 shares of common stock on the seven (7) month anniversary of the Agreement, and (iii) an additional 100,000 shares of common stock on the ten (10) month anniversary of the Agreement. The Agreement contains a blocker provision that prohibits the issuance of common stock to Bespoke during the term of the Agreement which would cause the beneficial ownership of Bespoke and its affiliates to exceed 9.99% of the Company's outstanding shares of common stock.

The Agreement has an initial term of one (1) year, unless earlier terminated by the Company. The Company may terminate the Agreement before the end of the initial term upon 30 calendar days' notice to Bespoke. The Agreement provides for indemnification of Bespoke, its officers, directors, members, employees, affiliates, and agents by the Company of all losses, expenses, damages and costs, including reasonable attorneys' fees, resulting from any act, action or omission, except for acts of Bespoke of willful misconduct, bad faith or gross negligence related to the Agreement.

On March 29, 2019, the Company completed a bridge financing, pursuant to which the Company issued to two accredited investors convertible notes on the aggregate principal amount of $225,000 (the "Notes") and seven-year warrants (the "Warrant") to purchase an aggregate of 90,000 shares of the Company's common stock or series C preferred stock at an exercise price of the *lesser* of: (a) 80% (*i.e*., a 20% discount) of the exercise price per share of the warrants to purchase shares of the Company's capital stock issued in the first equity financing of the Company following the date of issuance, or (b) $4.80, with a stipulation that in no event will the exercise price be less than $3.00 per warrant share.

The principal amount and all accrued but unpaid interest on the Notes are due and payable on the date (the "Maturity Date") that is the earlier of the (i) 5-year anniversary of the date of issuance, or (ii) the date the Company completes an equity financing pursuant to which the Company issues and sells shares of capital stock resulting in aggregate proceeds of at least $2,000,000 (a "Qualified Financing"). The Notes bear interest at a rate of 6% per annum, payable on the Maturity Date. To the extent not previously converted, on the Maturity Date, the investors will receive, at the option of each the investor, either (a) cash equal to the original principal amount of the Note and interest then accrued and unpaid thereon, or (b) shares of common stock or series C convertible preferred stock of the Company, at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company as of the Maturity Date, as determined in good faith by the Company's board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, as of the Maturity Date on a fully diluted basis, and (y) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the capital stock of the Company. Upon consummation of a Qualified Financing, each investor may elect to have the outstanding principal and accrued but unpaid interest thereon converted into (a) shares of the same class and series of equity securities sold in such Qualified Financing, (b) shares of series C convertible preferred stock or (c) common stock, at a price per share equal to the lesser of: (a) 80% of the price per share at which such securities are sold in such Qualified Financing and (b) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the Company's capital stock.

In no event will the number of shares to be issued upon (i) exercise of this Warrants, (ii) conversion of the Notes exceed, in the aggregate, 9.9% of the total shares outstanding or the voting power outstanding on the date immediately preceding the date of issuance.

Index to Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (as presently in effect) (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 17, 2015).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
3.3	Certificate of Amendment of Certificate of Incorporation (creating the series C preferred stock) (incorporated by reference to Exhibit 3.3 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 7, 2017)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
4.2	Form of Warrant Agency Agreement, (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission on October 31, 2017)
4.3	Form of Unit Purchase Option (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission on October 18, 2017)
4.4	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission on October 18, 2017)
10.1	Fourteenth Amended and Restated Securities Purchase Agreement, dated June 16, 2014, by and between NanoVibronix, Inc. and Globis Overseas Fund, Ltd. (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.2	Fourteenth Amended and Restated Securities Purchase Agreement, dated December 11, 2014, by and between NanoVibronix, Inc. and Globis Capital Partners, L.P. (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.3	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2014, by NanoVibronix, Inc. in favor of and Globis Overseas Fund, Ltd. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.4	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2014, by NanoVibronix, Inc. in favor of and Globis Capital Partners, L.P. (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.5	Form of Amended and Restated 2013 and 2014 Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.13 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2014)

10.6+	NanoVibronix, Inc. 2004 Global Share Option Plan (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.7+	Personal Employment Agreement, dated March 1, 2008, by and between Nano-Vibronix (Israel 2003) Ltd and Jona Zumeris (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.8+	Form of Indemnification Agreement between NanoVibronix, Inc. and certain of its officers and directors (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.9	Amendment to Subscription Agreement Convertible Promissory Notes, dated February 28, 2014, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.10	Second Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2014, by and between NanoVibronix, Inc. and the holders signatory thereto (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.11	Third Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2014, by and between NanoVibronix, Inc. and the holders signatory thereto (incorporated by reference to Exhibit 10.20 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014)
10.12+	NanoVibronix, Inc. 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.27 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
10.13+	First Amendment to Personal Employment Agreement, dated June 16, 2014, by and between NanoVibronix, Inc. and Dr. Jona Zumeris (incorporated by reference to Exhibit 10.29 to Amendment No. 8 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 23, 2014)
10.14	Services Agreement, dated March 25, 2015, by and between Multigon Industries, Inc. and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.35 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.15+	Employment Agreement, dated March 25, 2015, by and between William Stern and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.36 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.16+	Warrant to Purchase Common Stock, dated March 25, 2015 (incorporated by reference to Exhibit 10.38 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.17+	Letter Agreement, dated March 25, 2015, by and between NanoVibronix, Inc. and Martin Goldstein (incorporated by reference to Exhibit 10.39 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.18+	Form of Incentive Stock Option Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.40 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).

10.19+	Form of Nonqualified Stock Option Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.41 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.20+	Form of Restricted Stock Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.42 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.21+	Form of 3(i) Award Agreement under the Israeli Appendix to the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.22+	Form of 102 Award Agreement under the Israeli Appendix to the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.44 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.23+	Employment Agreement, dated October 13, 2016, by and between NanoVibronix, Inc. and Brian Murphy (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016).
10.24	Form of Amendment to Warrant to Purchase Common Stock, effective as of January 27, 2017 (incorporated by reference to Exhibit 10.46 to the Annual Report on Form 10-K filed with the Securities Exchange Commission on March 31, 2017).
10.25	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2017).
10.26	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2017).
10.27	Convertible Promissory Note, dated March 23, 2017, by and between NanoVibronix, Inc. and an individual investor (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2017).
10.28	Warrant to Purchase Common Stock, dated March 23, 2017, by and between NanoVibronix, Inc. and an individual investor (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2017).
10.29+	First Amendment to Nonqualified Stock Option Agreement, dated March 30, 2017, between NanoVibronix, Inc. and Ira A. Greenstein (incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K filed with the Securities Exchange Commission on March 31, 2017).
10.30+	First Amendment to Nonqualified Stock Option Agreement, dated March 30, 2017, between NanoVibronix, Inc. and Ira A. Greenstein (incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K filed with the Securities Exchange Commission on March 31, 2017).
10.31+	Offer Letter, dated October 14, 2016, between NanoVibronix, Inc. and Christopher M. Fashek (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016).
10.32+	Nonqualified Stock Option Agreement, dated October 14, 2016, between NanoVibronix, Inc. and Christopher M. Fashek (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016).

10.33	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017).
10.34	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017).
10.35	Form of Letter Agreement, dated September 7, 2017, between NanoVibronix, Inc. and holders of the 2017 Notes (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-KA/filed with the Securities and Exchange Commission on September 14, 2017).
10.36*	Consulting Agreement dated as of February 21,2019, between Nanovibronix, Inc and Bespoke Growth Partners, Inc.
10.37*	Convertible Promissory Note
10.38*	Convertible Promissory Note
10.39*	Form of Warrant
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
23.1*	Consent of Marcum, LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Kost, Forer, Gabbay & Kasierer, a member firm of Ernst & Young Global, Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101 *	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2017, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Stockholders' Deficiency, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.

* Filed herewith.
\+ Management contract or compensatory plan or arrangement.

SIGNATURES

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

NANOVIBRONIX, INC.

By: /s/ BRIAN MURPHY
Brian Murphy
Chief Executive Officer

Date: April 15, 2019

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

Signature	Title	Date
/s/ BRIAN MURPHY Brian Murphy	Chief Executive Officer and Director (principal executive officer)	April 15, 2019
/s/ STEPHEN BROWN Stephen Brown	Chief Financial Officer, (principal financial and accounting officer)	April 15, 2019
/s/ CHRISTOPHER FASHEK Christopher Fashek	Chairman of the Board of Directors	April 15, 2019
/s/ MARTIN GOLDSTEIN Martin Goldstein	Director	April 15, 2019
/s/ HAROLD JACOB M.D. Harold Jacob, M.D.	Director	April 15, 2019
/s/ MICHAEL FERGUSON Michael Ferguson	Director	April 15, 2019
/s/ THOMAS R. MIKA Thomas R. Mika	Director	April 15, 2019

***Bespoke** is **Money...**™*

CONSULTING AGREEMENT

This Consulting Agreement (the "**Agreement**") is made as of this 21st day of February 2019 ("**Effective Date**"), by and between NanoVibronix, Inc., a Delaware Corporation, 9 Derech Hashalom Street, Nesher, Israel with a United States office at 525 Executive Boulevard, Elmsford, NY 10523 ("**NAOV**" or the **"Company"),** and Bespoke Growth Partners, Inc., a Delaware Corporation, 625 N. Flagler Drive, Ste. 600, West Palm Beach, FL 33401 ("**Bespoke**," or the "**Consultant**").Company and/or Consultant may each be referred to herein as a **"Party."** and collectively as the **"Parties."**

WHEREAS, NAOV is focused on the manufacture and sale of noninvasive, biological response-activating devices that target biofilm prevention, wound healing and pain therapy;

WHEREAS, the Company's products include UroShield™, an ultrasound-based product to prevent bacterial colonization and biofilm in urinary catheters, enhance antibiotic efficacy and decrease pain and discomfort associated with urinary catheter use; PainShield™, a patch-based therapeutic ultrasound technology to treat pain, muscle spasm, and joint contractures; and WoundShield™, a patch-based therapeutic ultrasound device, which facilitates tissue regeneration and wound healing;

WHEREAS, NAOV is exploring opportunities to grow its business lines and may potentially seek certain strategic opportunities to strengthen the Company's growth prospects and balance sheet;

WHEREAS, Consultant has substantial corporate advisory expertise for public companies including in the areas of bioscience, pharmaceuticals and healthcare including medical devices and general business and management consulting and the Company has contacted Consultant to assist Company management with its development plans;

WHEREAS, Company desires to retain Consultant to (i) assist the Company with its plans to expand its business; (ii) work towards institutionalizing the Company from an investor perspective; (iii) develop and implement market-focused strategies and incorporate best practices; and (iv) furnish additional ongoing management and business consulting services aimed at enhancing Company's business (collectively, the **"Consulting Services");**

WHEREAS, Consultant desires to be engaged by Company and to provide the Consulting Services pursuant to such engagement; and

NOW, THEREFORE, in consideration of the premises and the mutual covenants hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is acknowledged, and intending to be legally bound hereby, Consultant and Company agree as follows:

1. **TERM.** This Agreement shall commence on the date hereof along with receipt of the fees defined in Section 4 below and shall extend thereafter for one (1) year (the "Term"). Unless immediate termination is otherwise specifically permitted herein or by applicable law, the Company may cancel this Agreement by providing thirty (30) calendar day's written notice to the other Party (a **"Termination Notice").** Notwithstanding, in the event of a Termination Notice, all of the compensation mentioned in this Agreement and issued to consultant up to and including fifteen (15) days following the Termination Notice [" **Shares**," as defined in Section 4(a) and (c) below] shall be deemed earned (or immediately due and payable).

2. **CONSULTING SERVICES.** Company expressly agrees and further acknowledges that Consultant's obligations are to be performed in a commercially reasonable manner and that the execution of this Agreement cannot and does not guaranty any particular success or result. Consultant agrees to act reasonably and in good faith to assist the Company *via* the Consulting Services, which may include, always at the Company's specific request:

(a) Providing consulting and liaison services to the Company relating to the further development and implementation of its corporate and business plan;

(b) Possible planning, review and creation of certain corporate communications and presentations, the issuance of which shall be subject to applicable United States securities laws, including those governing disclosure, private placements and public offerings;

(c) Advising the Company with respect to potential future merger and/or acquisition activities, alliances, joint-ventures, and/or its financial structure and that of its divisions or subsidiaries;

(d) Assessment of the Company's current shareholder base and working with the Company to introduce potential institutional investors and high-quality retail investors to the Company and educate such investors in regards to the current position and potential of the Company in accordance with the Company goal of achieving an appropriate investor mix of solid retail and institutional investors;

(e) Analysis of Company's current market strategies, recommendations, and implementation of best practices; and

(f) Such other Consulting Services and assistance as Consultant and Company shall mutually deem reasonably necessary or appropriate to enhance NAOV's business.

Company understands and acknowledges that the Consulting Services are not intended to, will not constitute, and should never be construed as, engaging in the provision of legal advice or broker-dealer activities to Company and that the Consultant shall have no authority to make 'offers' to sell Company's securities, make representations or warranties on Company's behalf or bind the Company in any way.

3. **APPROVAL OF INFORMATION.** Company shall furnish Consultant with such information as is reasonably required in order for Consultant to perform its duties hereunder (all such information so furnished, the **"Information").** Company recognizes and confirms that Consultant (i) will use, and rely primarily on, the Information and information available from generally recognized public sources (the **"Public Information")** in rendering its services without having independently verified the same; (ii) does not assume responsibility for the accuracy or completeness of the Information and Public Information; (iii) will not make an appraisal of any assets of Company; and/or (iv) will provide its advice hereunder based on the Information and the Public Information. It is the Company's responsibility to make certain that the Information to be furnished by Company, when delivered, will be true and correct in all material respects and will not contain any misstatement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements contained therein, in light of the circumstances under which they were made, not misleading. Consultant shall make no representations, warranties or guarantees on behalf of Company without Company's prior written consent.

4. **COMPENSATION.**

For the Consulting Services rendered during the Term, the following compensation/fees shall be due and owing the Consultant from the Company:

(a) Simultaneous with the execution of this Agreement, Company shall issue and immediately and irrevocably deliver to Consultant, Two Hundred Seventy-Five Thousand (275,000) restricted shares of Common Stock of the Company (the "**Shares**") and Fifty Thousand United States Dollars ($50,000 USD) (the **"Cash Fee**").

(b) The Shares and Cash Fee are deemed and agreed to be a commencement incentive and consideration now due and owing for Consultant entering into this Agreement and performing Consultant's duties during the Term of this Agreement. Company acknowledges that Consultant has foregone other opportunities to enter into this Agreement and to reserve sufficient resources to perform its duties throughout the Term (including preliminary research, diligence and infrastructure set up for Company's account), and that Company therefore derives immediate benefit as a result of these actions taken by the Consultant hereunder.

(c) If the Company has not previously terminated this Agreement pursuant to Section 1, on the three (3) month anniversary of this Agreement, Company shall issue and immediately and irrevocably deliver to Consultant or its designated assignee, Seventy-Five Thousand (75,000) additional restricted shares of Common Stock of the Company. Following such issuance of additional shares [as well as the additional shares as set forth in this Section 4(d) and (e)] all references to **"Shares"** herein shall also refer to such additional shares except thatSection 4(b) above is not applicable to the additional shares.

(d) If the Company has not previously terminated this Agreement pursuant to Section 1, on the seven (7) month anniversary of this Agreement, Company shall issue and immediately and irrevocably deliver to Consultant or its designated assignee, Two Hundred Thousand (200,000) additional restricted shares of Common Stock of the Company.

(e) If the Company has not previously terminated this Agreement pursuant to Section 1, on the ten (10) month anniversary of this Agreement, Company shall issue and immediately and irrevocably deliver to Consultant or its designated assignee, One Hundred Thousand (100,000) additional restricted shares of Common Stock of the Company.

(f) Consultant shall not be issued, at any time during the Term or any extension thereof, such number of shares of NAOV common stock that would result in beneficial ownership by the Consultant and its affiliates of more than 9.99% of the outstanding shares of Company Common Stock.

(g) The Company agrees to take any and all action(s) necessary to clear the Shares and each issuance of additional shares awarded to Consultant under this Section 4 of restriction upon presentation of any Rule 144 application by Consultant or its broker, including, without limitation, (i) authorizing the Company's transfer agent to remove the restrictive legend on the subject Shares or additional shares, (ii) expediting the acquisition of a legal opinion from Company's authorized counsel at Company's expense (or, in the event Consultant uses its own counsel, at company's expense up to $500) favorably opining as to the removal of the restrictive legend, and (iii) cooperating and communicating with Consultant and its broker in order to use the Company's commercially reasonable best efforts to clear the subject shares of restriction as soon as possible after presentation of a Rule 144 application by Consultant or its broker to either the Company or its transfer agent. Further, the Company agrees not to unreasonably withhold or delay approval of any application filed by Consultant or its broker under Rule 144 to clear the subject shares or additional shares of restriction.

(h) The Company (i) agrees that its Board of Directors has approved this Agreement and that it will appropriately and timely disclose the issuance of the Shares as issued in its SEC filing(s) if required by applicable securities laws; (ii) shall provide Consultant with a true and correct copy of the Company Board Resolution authorizing the issuance of the Shares; and (iii) represents and warrants that the Shares issued to Consultant as compensation hereunder shall be validly issued, fully paid and non-assessable.

(i) The Parties shall negotiate and agree in good faith regarding Consultant's compensation package for any consulting services to be provided beyond the scope of this Agreement and/or beyond the Term depending upon the Company's needs at such time and the services being requested of Consultant.

(j) The registration name on all stock certificates delivered to Consultant shall be "Bespoke Growth Partners, Inc." unless Consultant advises otherwise in a writing signed by its CEO.

5. **LIMITATION OF ENGAGEMENT.** Company acknowledges that Consultant has been retained only by Company, that Consultant is providing Consulting Services hereunder as an independent contractor (and not in any fiduciary or agency capacity) and that Company's engagement of Consultant is not deemed to be on behalf of, and is not intended to confer rights upon, any shareholder, owner or partner of NAOV or any other person not a Party hereto as against Consultant or any of its affiliates, or any of its or their respective officers, directors, controlling persons, employees or agents. Unless otherwise expressly agreed in writing by Consultant, no one other than the Company is authorized to rely upon this Agreement or any other statements or conduct of Consultant. Company acknowledges that any recommendation or advice, written or oral, given by Consultant to the Company in connection with Consultant's engagement is intended solely for the benefit and use of the Company, and any such recommendation or advice is not on behalf of, and shall not confer any rights or remedies upon, any other person or be used or relied upon for any other purpose. Consultant shall not have the authority to make any commitment binding on the Company. Company in its sole discretion, shall have the right to reject any investor introduced to it by Consultant.

Company acknowledges that neither the price of the company's stock, nor the trading volume thereof measure Consultant's performance hereunder.

6 . **CONFIDENTIALITY.** Other than as required by applicable law, neither Consultant nor any of its consultants, employees, agents, and/or officers or directors shall disclose any knowledge or information they may obtain in the course of performing the Consulting Services, which knowledge or information might concern confidential or material, non-public affairs of Company without the Company's prior consent.

7. **COMPLIANCE AND GOVERNING LAW.**

(a) NAOV, in connection with the issuance of any stock to Consultant hereunder, as may be applicable, shall be responsible for any and all compliance with applicable securities laws, rules and regulations, including, without limitation, the Act as well as all applicable filing requirements under the Securities Exchange Act of 1934 **("Exchange Act"),** and all state securities laws. Company recognizes and agrees that failure to timely make its Exchange Act filings will materially hinder the effectiveness of the Consulting Services and will constitute automatic grounds for cancellation by the Consultant and all compensation paid to Consultant up to and including the date of such failure shall be deemed fully earned by Consultant as of such date.

(b) This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.

(c) It is specifically understood that Consultant is not and does not hold itself out to be a 'broker/dealer' as that term is understood in applicable law (including the 'Paul Anka' SEC no-action letter dated July 24, 1991, and the 'Country Business, Inc.' SEC no-action letter dated November 8, 2006) in reference to the Company procuring financing sources and merger and/or acquisition candidates, and Consultant does not normally provide such services. Consultant may identify and introduce to the Company potential investors but will not be responsible for the structuring of any transaction with any such investor. Any obligation to pay compensation hereunder shall survive the merger, acquisition or other change in the form of entity of the Company and to the extent it remains unfulfilled shall be assigned and transferred to any successor to the Company. The Company agrees that no reference to the Consultant will be made in any filing, press release or advertisement of any financing without the express approval, in writing, of such release by Consultant, except as required at law. It is further understood that Company and not Consultant is responsible to perform any and all due diligence on any broker/dealer, lender, investor or merger or acquisition candidate introduced to Company by Consultant under this Agreement prior to Company receiving funds or closing on any transaction.

8. **NOTICE.** All notices and correspondence hereunder shall be in writing and sent by overnight delivery service, with all charges prepaid, to the applicable Party at the addresses set forth above, or by confirmed facsimile transmission (including, without limitation, computer generated facsimile) or by e-mail, as to each Party, to such address as any Party may from time-to-time designate for itself by notice in writing given to the other Party complying as to delivery with the terms of this Section 8. All such notices and correspondence shall be deemed given upon the earliest to occur of (i) if by e-mail, actual receipt; (ii) if sent by overnight delivery service, when received at the above stated addresses or when delivery is refused; or (iii) if sent by facsimile transmission or electronic mail, on the next business day or when receipt of such transmission is acknowledged or confirmed, whichever is earlier.

9. **INDEMNIFICATION.** Subject to Section 10 hereunder, Company agrees to indemnify, defend and hold harmless Consultant, its officers, directors, members, employees, affiliates, and agents against all losses, expenses, damages and costs, including reasonable attorneys' fees, resulting from any act, action or omission, except for acts of Consultant of willful misconduct, bad faith or gross negligence related to this Agreement.

10. **LIMITATIONS.** Any liability of Consultant and its officers, directors, controlling persons, employees or agents related to this Agreement shall not exceed Twenty-Five Thousand United States Dollars (USD $25,000), unless it is finally judicially determined that such liability resulted primarily from the gross negligence or willful misconduct of Consultant (in which case there shall be no such limitation). Subject to Section 7(a), any liability of Company and its officers, directors, controlling persons, employees or agents related to this Agreement shall not exceed the compensation (Shares) actually issued to Consultant by Company pursuant this Agreement, unless it is finally judicially determined that such liability resulted primarily from the gross negligence or willful misconduct of Company (in which case there shall be no such limitation). *No guarantees of NAOV stock performance express or implied have been made by or involving the Company or Consultant in connection with this Agreement, which Agreement memorializes the full extent of the relationship between the Company and Consultant.*

11. **EXPENSES.** Company will reimburse Consultant for its receipted expenses incurred in connection with the Consulting Services, if such expenses are approved in advance in writing (email confirmation is acceptable). Reimbursement shall be made within thirty (30) business days following receipt of Consultant's invoice. Company shall also reimburse Consultant for costs incurred by Consultant for collection of any fees due to Consultant under this Agreement, including but not limited to reasonable attorneys' fees and court costs.

12. **INDEPENDENT CONTRACTORS.** No agency, joint venture, partnership or employment shall be created by this Agreement, as the Parties are independent contractors with respect to one another. Neither Party shall have authority to act as an agent of the other or to otherwise bind the other to any agreement, commitment, obligation, contract, instrument, undertaking, arrangement, certificate or other matter. Each Party hereto shall refrain from making any representation intended to create an apparent agency, employment, partnership or joint venture relationship.

13. **MISCELLANEOUS.** This Agreement shall not be modified or amended except in writing signed by the Parties. This Agreement shall be binding upon and inure to the benefit of the Parties. This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersedes any prior agreements. If any provision of this Agreement is determined to be invalid or unenforceable in any respect, such determination will not affect such provision in any other respect, and the remainder of the Agreement shall remain in full force and effect. In the interpretation of this Agreement, the *'contra proferentem'* rule of construction will not apply (this Agreement being the product of negotiations between commercially sophisticated Parties) and this Agreement will therefore not be construed in favor of or against any Party by reason of the extent to which any Party or its professional advisors participated in the preparation and drafting hereof. This Agreement may be executed in counterparts (including e-mail or facsimile counterparts), each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties to this Consulting Agreement have hereunto set their hands and seal the day and year first above written.

Bespoke Growth Partners, Inc.

By: _____
Name: Mark H. Peikin, Esq.
Title: CEO
Duly Authorized

Nano Vibronix, Inc.

By: _____
Name: Brian Murphy
Title: CEO
Duly Authorized

[Signature Page 7 of 7 / Bespoke Growth Partners, Inc. / NAOV / Consulting Agreement / February 2019]

THIS NOTE AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR AN OPINION OF COUNSEL SATISFACTORY TO THE BORROWER THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR UNLESS SOLD PURSUANT TO RULE 144 UNDER SUCH ACT.

CONVERTIBLE PROMISSORY NOTE

$125,000 March 29, 2019

FOR VALUE RECEIVED, NanoVibronix, Inc., a Delaware corporation (the ***"Borrower"***), hereby promises to pay to the order of Globis Capital Partners, L.P. (***"Lender"***), the principal amount (***"Principal Amount"***) equal to $125,000 Interest on the unpaid portion of the Principal Amount shall be payable on the Maturity Date (as defined below) at a rate per annum equal to 6%.

1. Terms; Payment.

1.1 Terms. This Note is one of a number of similar notes (the ***"Other Notes"***) being issued and delivered by the Borrower to certain note holders (together with Lender, the "Note Holders") pursuant to a debt financing of up to $750,000

1.2 Payment. Unless this Note has been previously converted in accordance with the terms of Section 3 hereunder, the Principal Amount and all accrued but unpaid interest thereon shall be due and payable on the date that is the earlier of the (i) 5-year anniversary of the date hereof, or (ii) the date that the Borrower completes a Qualified Financing (as hereafter defined) (the "***Maturity Date***"). On the affirmative vote of the holders of at least two-thirds (2/3rds) of the outstanding aggregate Principal Amount of this Note and each of the Other Notes (the "***Required Holders***"), the Borrower may from time to time extend the Maturity Date of this Note and each of the Other Notes. All payments shall be made in lawful money of the United States of America at the principal office of the Borrower, or at such other place as the holder hereof may from time to time designate in writing to the Borrower. Payment shall be credited first to accrued interest due and payable and the remainder applied to principal. The Borrower hereby waives demand, notice, presentment, protest and notice of dishonor.

2. Representations and Warranties of Lender. In connection with the transactions provided for herein, Lender hereby represents and warrants to the Borrower that:

2.1 Purchase Entirely for Own Account. Lender acknowledges that this Note is issued to Lender in reliance upon Lender's representation to the Borrower that this Note will be acquired for investment for Lender's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that such Lender has no present intention of selling, granting any participation in, or otherwise distributing the same. By executing this Note, Lender further represents that Lender does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to this Note.

2.2 **Investment Experience.** Lender is an investor in securities of companies in the development stage and acknowledges that it, he or she is able to fend for itself, himself or herself, can bear the economic risk of its, his or her investment, and has such knowledge and experience in financial or business matters that it, he or she is capable of evaluating the merits and risks of the investment in this Note. Lender also represents it, he or she has not been organized solely for the purpose of acquiring this Note.

2.3 **Accredited Investor.** Lender is an "accredited investor" within the meaning of Rule 501 of Regulation D, as presently in effect, as promulgated by the Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended (the "Act").

2.4 **Restricted Securities.** Lender understands that this Note is characterized as a "restricted security" under the federal securities laws inasmuch as it is being acquired from the Borrower in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Act only in certain limited circumstances. In this connection, Lender represents that it is familiar with Rule 144 as promulgated by the SEC under the Act, as presently in effect, and understands the resale limitations imposed thereby and by the Act.

3. **Conversion of this Note.** This Note shall be convertible according to the following terms:

3.1 **Definitions.** The following terms shall have the meanings assigned below:

(a) ***"Change of Control"*** means any consolidation or merger of the Borrower with or into any other corporation or other entity or person, or any other corporate reorganization in which the Borrower shall not be the continuing or surviving entity of such reorganization or any transaction or series of related transactions by the Borrower in which in excess of 50% of the Borrower's voting power is transferred, or a sale of all or substantially all of the assets of the Borrower, other than any transaction or series of related transactions which is primarily for the purpose of financing the Borrower or a reincorporation of the Borrower.

(b) ***"Equity Financing"*** means the issuance and sale by the Borrower of shares of its Capital Stock, with the principal purpose of raising capital, for cash.

(c) ***"Equity Securities"*** means the Borrower's capital stock (the "Capital Stock") or any securities conferring the right to purchase such Capital Stock or securities convertible into, or exchangeable for (with or without additional consideration), such Capital Stock.

3.2 Qualified Financing. In the event the Borrower consummates an Equity Financing following the date of issuance of this Note pursuant to which it issues and sells shares of Capital Stock resulting in aggregate proceeds (excluding the conversion of this Note and each of the Other Notes) to the Borrower of at least $2,000,000 (a "***Qualified Financing***"), and provided that this Note remains outstanding at the time of such Qualified Financing, Lender may, upon 10 days' prior notice, elect to have the outstanding principal and unpaid accrued interest of this Note converted into shares of the same class and series of Equity Securities sold in such Qualified Financing, provided that the Lender may elect to receive shares of the Series C Convertible Preferred Stock of the Borrower instead of shares of common stock of the Borrower (the "***Common Stock***") to the extent that shares of Common Stock are issued in such Qualified Financing, at a price per share equal to the lesser of: (a) 80% (i.e., a 20% discount) of the price per share at which such securities are sold in such Qualified Financing and (b) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our Capital Stock. At least 10 business days prior to the closing of the Qualified Financing, the Borrower shall notify Lender in writing of the terms under which the Equity Securities of the Borrower will be sold in such financing. The conversion of this Note into Equity Securities under this Section 3.2 shall occur on the closing date of such Qualified Financing, and at the closing of the Qualified Financing, Lender shall execute a stock purchase agreement in the same form as that executed by the other investors of the Qualified Financing. Notwithstanding the foregoing in no event will the number of shares to be issued upon (i) conversion of this Note or the Other Notes, or (ii) upon exercise of the warrants to purchase capital stock of the Company issued to the Note Holders on the date hereof exceed, in the aggregate, 9.9% of the total shares outstanding or the voting power outstanding on the date immediately preceding the day hereof.

3.3 Change of Control. If prior to the Maturity Date, there is a Change of Control and this Note has not previously converted pursuant to Section 3.2, Lender may, upon 10 days' prior notice, elect to have this Note converted or repaid in one of the following two ways: (a) Lender may elect to receive from the Borrower an amount in cash equal to the sum of the original Principal Amount and interest then accrued and unpaid under the Note, or (b) Lender may elect to convert this Note plus all accrued and unpaid interest into shares of Common Stock or, if Lender so elects, into shares of the Series C Convertible Preferred Stock of the Borrower, immediately prior to the closing of such Change of Control at a price per share equal to the Change of Control Exchange Price. For purposes of the foregoing sentence, the "***Change of Control Exchange Price***" means the lesser of: (x) 80% (*i.e.*, a 20% discount) of the amount (expressed in dollars) equal to the quotient obtained by dividing (i) the estimated value of the Borrower implied by the exchange ratio set forth in the agreement governing such Change of Control, as determined in good faith by the Borrower's board of directors, by (ii) the aggregate number of outstanding shares of the Borrower's Common Stock, immediately prior to such Change of Control on a fully diluted basis, and (y) $5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our Capital Stock. In the event that Lender does not make an election within 10 days of the notice from the Borrower (with email being adequate notice), the Borrower shall determine, in its reasonable discretion, to convert or repay the Note, based upon whether the value of the consideration that would be payable to Lender in a Change of Control if Lender converted this Note is greater than the Principal Amount and accrued and unpaid interest on this Note.

3 . 4 **Maturity Date.** If on the Maturity Date this Note has not previously converted pursuant to Sections 3.2 or 3.3, Lender may, upon 10 days' prior notice, elect to have this Note converted or repaid in one of the following two ways: (a) Lender may elect to receive from the Borrower an amount in cash equal to the sum of the original Principal Amount and interest then accrued and unpaid under the Note, or (b) Lender may elect to convert this Note plus all accrued and unpaid interest into shares of Common Stock or, if Lender so elects, into shares of the Series C Convertible Preferred Stock of the Borrower, on the Maturity Date at a price per share equal to the Maturity Date Exchange Price. For purposes of the foregoing sentence, the "***Maturity Date Exchange Price***" means the lesser of: (x) 80% (*i.e*., a 20% discount) of the amount (expressed in dollars) equal to the quotient obtained by dividing (i) the estimated value of the Borrower as of the Maturity Date, as determined in good faith by the Borrower's board of directors, by (ii) the aggregate number of outstanding shares of the Borrower's Common Stock, as of the Maturity Date on a fully diluted basis, and (y) $5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our Capital Stock. In the event that Lender does not make an election within 10 days of the notice from the Borrower (with email being adequate notice), the Borrower shall determine, in its sole discretion, to convert or repay the Note.

3 . 5 **Additional Terms.** Upon the conversion of this Note, in lieu of any fractional shares to which Lender would otherwise be entitled, the Borrower shall pay Lender cash equal to such fraction multiplied by the issue price of such Equity Securities or Common Stock, as applicable. As promptly as practicable after the conversion of this Note, the Borrower at its expense will issue and deliver to Lender, upon surrender of this Note, a certificate or certificates for the number of full shares of Equity Securities or Common Stock, as applicable, issuable upon such conversion.

4. Miscellaneous.

4 . 1 **No Prepayments.** Except to the extent expressly permitted in writing by the Required Holders, the Borrower shall not be entitled to prepay any portion of the outstanding Principal Amount of this Note or any of the Other Notes.

4.2 **Successors and Assigns.** Except as otherwise provided herein, the terms and conditions of this Note shall inure to the benefit of and be binding upon the respective successors and assigns of the parties; *provided, however*, that neither party may assign its rights or obligations under this Note without the prior written consent of the other party. Nothing in this Note, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Note, except as expressly provided in this Note.

4 . 3 **Governing Law and Venue.** This Note shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to its conflicts of laws principles. Any disputes shall be resolved in the federal or state courts situated in New York, New York, with the prevailing party being entitled to attorneys' fees and reasonable costs.

4.4 **Notices.** All notices and other communications given or made pursuant hereto shall be in writing to the addresses set forth on the signature pages hereof and shall be deemed effectively given: (i) upon personal delivery to the party to be notified, (ii) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient; if not, then on the next business day, (iii) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one (1) day after deposit with an internationally recognized overnight courier, specifying next day delivery, with written verification of receipt.

4.5 **Severability.** If one or more provisions of this Note are held to be unenforceable under applicable law, such provision shall be excluded from this Note and the balance of this Note shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

4.6 **Further Assurance.** From time to time, the Borrower shall execute and deliver to Lender such additional documents and shall provide such additional information to Lender as Lender may reasonably require to carry out the terms of this Note, and any agreements executed in connection herewith, and to be informed of the financial and business conditions and prospects of the Borrower.

4.7 **Entire Agreement; Amendments and Waivers.** This Note constitutes the entire agreement of the parties, superseding and extinguishing all prior agreements and understandings, representations and warranties, relating to the subject matter hereof. Any provision of this Note may be amended, waived or modified upon the written consent of the Borrower and the Required Holders. Notwithstanding the foregoing, in the event an amendment, waiver, or modification of this Note adversely affects the rights of Lender in a manner different than the other Note Holders other than by virtue of the amount of principal and interest then outstanding owed to such persons, then the written consent of Lender shall also be required to enforce such amendment, waiver or modification.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Note is executed as of the date first above written.

THE "BORROWER":

March 29, 2019

NANOVIBRONIX, INC.,
a Delaware corporation

Address:
525 Executive Blvd
Elmsford NY 10523

By: /s/Stephen Brown
Name: Stephen Brown
Title: CFO

[*Convertible Promissory Note - Borrower's Signature Page*]

LENDER'S COUNTERPART SIGNATURE PAGE
TO
CONVERTIBLE PROMISSORY NOTE

The undersigned Lender agrees to be bound by the terms of the Convertible Promissory Note of NanoVibronix, Inc., a Delaware corporation, executed by the Borrower in favor of the undersigned Lender, and agrees to all of the terms thereof.

March 29, 2019

Address:

GLOBIS CAPITAL PARTNERS, L.P.

By: /s/Paul Packer
Name: Paul Packer
Title: Managing Partner

[*Convertible Promissory Note - Lender's Signature Page*]

Exhibit 10.38

THIS NOTE AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR AN OPINION OF COUNSEL SATISFACTORY TO THE BORROWER THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR UNLESS SOLD PURSUANT TO RULE 144 UNDER SUCH ACT.

CONVERTIBLE PROMISSORY NOTE

$100,000 March 29, 2019

FOR VALUE RECEIVED, NanoVibronix, Inc., a Delaware corporation (the ***"Borrower"***), hereby promises to pay to the order of AIGH Investment Partners, L.P. (***"Lender"***), the principal amount (***"Principal Amount"***) equal to $100,000 Interest on the unpaid portion of the Principal Amount shall be payable on the Maturity Date (as defined below) at a rate per annum equal to 6%.

1. Terms; Payment.

1.1 Terms. This Note is one of a number of similar notes (the ***"Other Notes"***) being issued and delivered by the Borrower to certain note holders (together with Lender, the "***Note Holders***") pursuant to a debt financing of up to $750,000

1.2 Payment. Unless this Note has been previously converted in accordance with the terms of Section 3 hereunder, the Principal Amount and all accrued but unpaid interest thereon shall be due and payable on the date that is the earlier of the (i) 5-year anniversary of the date hereof, or (ii) the date that the Borrower completes a Qualified Financing (as hereafter defined) (the "***Maturity Date***"). On the affirmative vote of the holders of at least two-thirds (2/3rds) of the outstanding aggregate Principal Amount of this Note and each of the Other Notes (the "***Required Holders***"), the Borrower may from time to time extend the Maturity Date of this Note and each of the Other Notes. All payments shall be made in lawful money of the United States of America at the principal office of the Borrower, or at such other place as the holder hereof may from time to time designate in writing to the Borrower. Payment shall be credited first to accrued interest due and payable and the remainder applied to principal. The Borrower hereby waives demand, notice, presentment, protest and notice of dishonor.

2. Representations and Warranties of Lender. In connection with the transactions provided for herein, Lender hereby represents and warrants to the Borrower that:

2.1 Purchase Entirely for Own Account. Lender acknowledges that this Note is issued to Lender in reliance upon Lender's representation to the Borrower that this Note will be acquired for investment for Lender's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that such Lender has no present intention of selling, granting any participation in, or otherwise distributing the same. By executing this Note, Lender further represents that Lender does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to this Note.

2.2 **Investment Experience.** Lender is an investor in securities of companies in the development stage and acknowledges that it, he or she is able to fend for itself, himself or herself, can bear the economic risk of its, his or her investment, and has such knowledge and experience in financial or business matters that it, he or she is capable of evaluating the merits and risks of the investment in this Note. Lender also represents it, he or she has not been organized solely for the purpose of acquiring this Note.

2.3 **Accredited Investor.** Lender is an "accredited investor" within the meaning of Rule 501 of Regulation D, as presently in effect, as promulgated by the Securities and Exchange Commission (the "***SEC***") under the Securities Act of 1933, as amended (the "Act").

2.4 **Restricted Securities.** Lender understands that this Note is characterized as a "restricted security" under the federal securities laws inasmuch as it is being acquired from the Borrower in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Act only in certain limited circumstances. In this connection, Lender represents that it is familiar with Rule 144 as promulgated by the SEC under the Act, as presently in effect, and understands the resale limitations imposed thereby and by the Act.

3. **Conversion of this Note.** This Note shall be convertible according to the following terms:

3.1 **Definitions.** The following terms shall have the meanings assigned below:

(a) ***"Change of Control"*** means any consolidation or merger of the Borrower with or into any other corporation or other entity or person, or any other corporate reorganization in which the Borrower shall not be the continuing or surviving entity of such reorganization or any transaction or series of related transactions by the Borrower in which in excess of 50% of the Borrower's voting power is transferred, or a sale of all or substantially all of the assets of the Borrower, other than any transaction or series of related transactions which is primarily for the purpose of financing the Borrower or a reincorporation of the Borrower.

(b) ***"Equity Financing"*** means the issuance and sale by the Borrower of shares of its Capital Stock, with the principal purpose of raising capital, for cash.

(c) ***"Equity Securities"*** means the Borrower's capital stock (the "***Capital Stock***") or any securities conferring the right to purchase such Capital Stock or securities convertible into, or exchangeable for (with or without additional consideration), such Capital Stock.

3.2 Qualified Financing. In the event the Borrower consummates an Equity Financing following the date of issuance of this Note pursuant to which it issues and sells shares of Capital Stock resulting in aggregate proceeds (excluding the conversion of this Note and each of the Other Notes) to the Borrower of at least $2,000,000 (a "***Qualified Financing***"), and provided that this Note remains outstanding at the time of such Qualified Financing, Lender may, upon 10 days' prior notice, elect to have the outstanding principal and unpaid accrued interest of this Note converted into shares of the same class and series of Equity Securities sold in such Qualified Financing, provided that the Lender may elect to receive shares of the Series C Convertible Preferred Stock of the Borrower instead of shares of common stock of the Borrower (the "***Common Stock***") to the extent that shares of Common Stock are issued in such Qualified Financing, at a price per share equal to the lesser of: (a) 80%*i*(*e*., a 20% discount) of the price per share at which such securities are sold in such Qualified Financing and (b) $4.00 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our Capital Stock. At least 10 business days prior to the closing of the Qualified Financing, the Borrower shall notify Lender in writing of the terms under which the Equity Securities of the Borrower will be sold in such financing. The conversion of this Note into Equity Securities under this Section 3.2 shall occur on the closing date of such Qualified Financing, and at the closing of the Qualified Financing, Lender shall execute a stock purchase agreement in the same form as that executed by the other investors of the Qualified Financing. Notwithstanding the foregoing in no event will the number of shares to be issued upon (i) conversion of this Note or the Other Notes, or (ii) upon exercise of the warrants to purchase capital stock of the Company issued to the Note Holders on the date hereof exceed, in the aggregate, 9.9% of the total shares outstanding or the voting power outstanding on the date immediately preceding the day hereof.

3.3 Change of Control. If prior to the Maturity Date, there is a Change of Control and this Note has not previously converted pursuant toSection 3.2, Lender may, upon 10 days' prior notice, elect to have this Note converted or repaid in one of the following two ways: (a) Lender may elect to receive from the Borrower an amount in cash equal to the sum of the original Principal Amount and interest then accrued and unpaid under the Note, or (b) Lender may elect to convert this Note plus all accrued and unpaid interest into shares of Common Stock or, if Lender so elects, into shares of the Series C Convertible Preferred Stock of the Borrower, immediately prior to the closing of such Change of Control at a price per share equal to the Change of Control Exchange Price. For purposes of the foregoing sentence, the "***Change of Control Exchange Price***" means the lesser of: (x) 80% (*i.e*., a 20% discount) of the amount (expressed in dollars) equal to the quotient obtained by dividing (i) the estimated value of the Borrower implied by the exchange ratio set forth in the agreement governing such Change of Control, as determined in good faith by the Borrower's board of directors, by (ii) the aggregate number of outstanding shares of the Borrower's Common Stock, immediately prior to such Change of Control on a fully diluted basis, and (y) $5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our Capital Stock. In the event that Lender does not make an election within 10 days of the notice from the Borrower (with email being adequate notice), the Borrower shall determine, in its reasonable discretion, to convert or repay the Note, based upon whether the value of the consideration that would be payable to Lender in a Change of Control if Lender converted this Note is greater than the Principal Amount and accrued and unpaid interest on this Note.

3 . 4 **Maturity Date.** If on the Maturity Date this Note has not previously converted pursuant to Sections 3.2 or 3.3, Lender may, upon 10 days' prior notice, elect to have this Note converted or repaid in one of the following two ways: (a) Lender may elect to receive from the Borrower an amount in cash equal to the sum of the original Principal Amount and interest then accrued and unpaid under the Note, or (b) Lender may elect to convert this Note plus all accrued and unpaid interest into shares of Common Stock or, if Lender so elects, into shares of the Series C Convertible Preferred Stock of the Borrower, on the Maturity Date at a price per share equal to the Maturity Date Exchange Price. For purposes of the foregoing sentence, the "***Maturity Date Exchange Price***" means the lesser of: (x) 80% (*i.e*., a 20% discount) of the amount (expressed in dollars) equal to the quotient obtained by dividing (i) the estimated value of the Borrower as of the Maturity Date, as determined in good faith by the Borrower's board of directors, by (ii) the aggregate number of outstanding shares of the Borrower's Common Stock, as of the Maturity Date on a fully diluted basis, and (y) $5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our Capital Stock. In the event that Lender does not make an election within 10 days of the notice from the Borrower (with email being adequate notice), the Borrower shall determine, in its sole discretion, to convert or repay the Note.

3 . 5 **Additional Terms.** Upon the conversion of this Note, in lieu of any fractional shares to which Lender would otherwise be entitled, the Borrower shall pay Lender cash equal to such fraction multiplied by the issue price of such Equity Securities or Common Stock, as applicable. As promptly as practicable after the conversion of this Note, the Borrower at its expense will issue and deliver to Lender, upon surrender of this Note, a certificate or certificates for the number of full shares of Equity Securities or Common Stock, as applicable, issuable upon such conversion.

4. Miscellaneous.

4 . 1 **No Prepayments.** Except to the extent expressly permitted in writing by the Required Holders, the Borrower shall not be entitled to prepay any portion of the outstanding Principal Amount of this Note or any of the Other Notes.

4.2 **Successors and Assigns.** Except as otherwise provided herein, the terms and conditions of this Note shall inure to the benefit of and be binding upon the respective successors and assigns of the parties; *provided, however*, that neither party may assign its rights or obligations under this Note without the prior written consent of the other party. Nothing in this Note, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Note, except as expressly provided in this Note.

4 . 3 **Governing Law and Venue.** This Note shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to its conflicts of laws principles. Any disputes shall be resolved in the federal or state courts situated in New York, New York, with the prevailing party being entitled to attorneys' fees and reasonable costs.

4.4 **Notices.** All notices and other communications given or made pursuant hereto shall be in writing to the addresses set forth on the signature pages hereof and shall be deemed effectively given: (i) upon personal delivery to the party to be notified, (ii) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient; if not, then on the next business day, (iii) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one (1) day after deposit with an internationally recognized overnight courier, specifying next day delivery, with written verification of receipt.

4.5 **Severability.** If one or more provisions of this Note are held to be unenforceable under applicable law, such provision shall be excluded from this Note and the balance of this Note shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

4.6 **Further Assurance.** From time to time, the Borrower shall execute and deliver to Lender such additional documents and shall provide such additional information to Lender as Lender may reasonably require to carry out the terms of this Note, and any agreements executed in connection herewith, and to be informed of the financial and business conditions and prospects of the Borrower.

4.7 **Entire Agreement; Amendments and Waivers.** This Note constitutes the entire agreement of the parties, superseding and extinguishing all prior agreements and understandings, representations and warranties, relating to the subject matter hereof. Any provision of this Note may be amended, waived or modified upon the written consent of the Borrower and the Required Holders. Notwithstanding the foregoing, in the event an amendment, waiver, or modification of this Note adversely affects the rights of Lender in a manner different than the other Note Holders other than by virtue of the amount of principal and interest then outstanding owed to such persons, then the written consent of Lender shall also be required to enforce such amendment, waiver or modification.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Note is executed as of the date first above written.

THE "BORROWER":

March 29, 2019

NANOVIBRONIX, INC.,
a Delaware corporation

Address:
525 Executive Blvd
Elmsford, NY 10523

By: /s/Stephen Brown
Name: Stephen Brown
Title: CFO

[*Convertible Promissory Note - Borrower's Signature Page*]

LENDER'S COUNTERPART SIGNATURE PAGE
TO
CONVERTIBLE PROMISSORY NOTE

The undersigned Lender agrees to be bound by the terms of the Convertible Promissory Note of NanoVibronix, Inc., a Delaware corporation, executed by the Borrower in favor of the undersigned Lender, and agrees to all of the terms thereof.

March 29, 2019

Address:

AIGH INVESTMENT PARTNERS, L.P.

By: /s/Orin Hirschman
Name: Orin Hirschman
Title: Managing Partner

[*Convertible Promissory Note - Lender's Signature Page*]

NEITHER THE ISSUANCE AND SALE OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE NOR THE SECURITIES INTO WHICH THESE SECURITIES ARE EXERCISABLE HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR (B) AN OPINION OF COUNSEL TO THE HOLDER (IF REQUESTED BY THE COMPANY), IN A FORM REASONABLY ACCEPTABLE TO THE COMPANY, THAT REGISTRATION IS NOT REQUIRED UNDER SAID ACT OR (II) UNLESS SOLD OR ELIGIBLE TO BE SOLD PURSUANT TO RULE 144 OR RULE 144A UNDER SAID ACT. NOTWITHSTANDING THE FOREGOING, THE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN OR FINANCING ARRANGEMENT SECURED BY THE SECURITIES.

NANOVIBRONIX, INC.

Warrant To Purchase Capital Stock

Warrant No.: 2019-[__]
Date of Issuance: March 29, 2019 ("***Issuance Date***")

NanoVibronix, Inc., a Delaware corporation (the "***Company***"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [_____], the registered holder hereof or its permitted assigns (the "***Holder***"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon exercise of this Warrant to Purchase Capital Stock (including any Warrants to Purchase Capital Stock issued in exchange, transfer or replacement hereof, this "***Warrant***"), at any time or times after the date hereof, but not after 11:59 p.m., New York time, on March 29, 2026, at the election of the Holder, [_____] ([_____]) (subject to adjustment as provided herein) fully paid and nonassessable shares of (i) Common Stock (as defined below), (ii) Series C Convertible Preferred Stock (as defined below) or (iii) a combination of Common Stock and Series C Convertible Preferred Stock (collectively, the "***Warrant Shares***"). For the avoidance of doubt, the maximum number of shares of Common Stock and Series C Convertible Preferred Stock that may be issued under this Warrant is [_____] ([_____]) (subject to adjustment as provided herein).

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof, this Warrant may be exercised by the Holder on any day after the Issuance Date, in whole or in part, by delivery (whether via facsimile or otherwise) of a written notice, in the form attached hereto as **Exhibit A** (the "***Exercise Notice***"), of the Holder's election to exercise this Warrant. Within one (1) Business Day following an exercise of this Warrant as aforesaid, the Holder shall deliver payment to the Company of an amount in cash by wire transfer of immediately available funds equal to the Exercise Price in effect on the date of such exercise multiplied by the number of Warrant Shares as to which this Warrant was so exercised or, if available, in the manner set forth in Section 1(c) below (the "***Aggregate Exercise Price***"). The Holder shall not be required to deliver the original of this Warrant in order to effect an exercise hereunder. Execution and delivery of an Exercise Notice with respect to less than all of the Warrant Shares shall have the same effect as cancellation of the original of this Warrant and issuance of a new Warrant evidencing the right to purchase the remaining number of Warrant Shares. Execution and delivery of an Exercise Notice for all of the then-remaining Warrant Shares shall have the same effect as cancellation of the original of this Warrant after delivery of the Warrant Shares in accordance with the terms hereof. On or before the first (1st) Business Day following the date on which the Company has received an Exercise Notice and payment of the Aggregate Exercise Price for the number of Warrant Shares for which this Warrant was so exercised, the Company shall transmit by facsimile an acknowledgment of confirmation of receipt of such Exercise Notice to the Holder and the Company's transfer agent for the Warrant Shares, if any. On or before the third (3rd) Business Day following the date on which the Company has received such Exercise Notice and payment of the Aggregate Exercise Price for the number of Warrant Shares for which this Warrant was so exercised, the Company shall issue and deliver to the Holder or, at the Holder's instruction pursuant to the Exercise Notice, the Holder's agent or designee, in each case, sent by reputable overnight courier to the address as specified in the applicable Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee (as indicated in the applicable Exercise Notice), for the number of shares of Common Stock or Series C Convertible Stock to which the Holder is entitled pursuant to such exercise. Upon delivery of an Exercise Notice and payment of the Aggregate Exercise Price for the number of Warrant Shares for which this Warrant was so exercised, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the certificates evidencing such Warrant Shares.

(b) Exercise Price. For purposes of this Warrant, "***Exercise Price***" means a price per Warrant Share equal to the *lesser* of: (a) 80% (*i.e.*, a 20% discount) of the exercise price per warrant share of the warrants to purchase shares of capital stock of the Company issued in the first Equity Financing of the Company following the Issuance Date, or (b) $4.80, subject to adjustment as provided herein. Nowithstanding anything contained herein to the contrary, in no event will the exercise price be less than $3.00 per Warrant Share.

(c) Cashless Exercise. If at any time after the six month anniversary of the original Issuance Date of this Warrant, there is no effective registration statement under the Securities Act of 1933, as amended (the "***Securities Act***"), registering the resale of the Common Stock underlying this Warrant by the Holder, then this Warrant may also be exercised, in whole or in part, by means of a "cashless exercise," in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y - \left(\frac{(A)(Y)}{B} \right)$$

Where X= the number of Warrant Shares to be issued to the Holder.

Y= the number of Warrant Shares purchasable upon exercise of all of the Warrant or, if only a portion of the Warrant is being exercised, the portion of the Warrant being exercised.

A= the Exercise Price.

B= the Per Share Market Value of one Warrant Share on the Business Day immediately preceding the date of such election.

(d) Fractional Shares. The Company shall not be required to issue or cause to be issued fractional Warrant Shares on the exercise of this Warrant. If any fraction of a Warrant Share would, except for the provisions of this Section, be issuable upon exercise of this Warrant, the number of Warrant Shares to be issued will be rounded up to the nearest whole share.

(e) Insufficient Authorized Shares. From and after the Issuance Date, the Company shall at all times keep reserved for issuance under this Warrant a number of shares of Common Stock and Series C Convertible Preferred Stock as shall be necessary to satisfy the Company's obligation to issue shares of Common Stock and Series C Convertible Preferred Stock hereunder. If, notwithstanding the foregoing, and not in limitation thereof, at any time while this Warrant remains outstanding the Company does not have a sufficient number of authorized and unreserved shares of Common Stock and Series C Convertible Preferred Stock (an "***Authorized Share Failure***") to satisfy its obligation to reserve for issuance upon exercise of this Warrant (the "***Required Reserve Amount***"), then the Company shall promptly take all action necessary to increase the Company's authorized shares of Common Stock or Series C Convertible Preferred Stock, as applicable, to an amount sufficient to allow the Company to reserve the Required Reserve Amount. Without limiting the generality of the foregoing sentence, if the approval of the stockholders of the Company is required, as soon as practicable after the date of the occurrence of an Authorized Share Failure, but in no event later than ninety (90) days after the occurrence of such Authorized Share Failure, the Company shall hold a meeting of its stockholders for the approval of an increase in the number of authorized shares of Common Stock or Series C Convertible Preferred Stock. In connection with such meeting, the Company shall provide each stockholder with a proxy statement and shall use its reasonable best efforts to solicit its stockholders' approval of such increase in authorized shares of Common Stock or Series C Convertible Preferred Stock, and to cause its board of directors to recommend to the stockholders that they approve such proposal.

(f) Holder's Exercise Limitations. The Company shall not affect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 1 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Exercise Notice, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock or Series C Convertible Preferred Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock and Series C Convertible Preferred Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 1(f), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 1(f) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 1(f), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Business Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "***Beneficial Ownership Limitation***" shall be 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock or Series C Convertible Preferred Stock issuable upon exercise of this Warrant. The Holder, upon not less than 61 days' prior written notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 1(f), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock or Series C Convertible Preferred Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 1(f) shall continue to apply. Any such increase or decrease will not be effective until the 61st day after such written notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 1(f) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant. The Beneficial Ownership Limitation provisions of this Section 1(f) may be waived at the election of the Holder upon not less than 61 days' prior written notice to the Company. Any such waiver will not be effective and the provisions of this paragraph shall continue to apply until the 61st day (or later, if stated in the notice) after such notice of waiver is delivered to the Company. Notwithstanding anything herein to the contrary, in no event will the number of shares to be issued upon (i) exercise of this Warrant, (ii) conversion of the notes issued on the date hereof to the Holder and [_____], in the aggregate principal amount of $250,000, and (iii) exercise of the warrant to purchase capital stock of the Company issued to [_____] on the date hereof exceed, in the aggregate, 9.9% of the total shares outstanding or the voting power outstanding on the date immediately preceding the day hereof.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. Without limiting any provision of Section 4, if the Company, at any time after the Issuance Date, (i) pays a stock dividend on one or more classes of its then outstanding shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, (ii) subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its then outstanding shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, into a larger number of shares or (iii) combines (by combination, reverse stock split or otherwise) one or more classes of its then outstanding shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, into a smaller number of shares, then in each such case (A) the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock or Series C Convertible Preferred Stock, as the case may, outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, outstanding immediately after such event and (B) the number of shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, for which this Warrant is exercisable immediately after the occurrence of any such event shall be adjusted to equal the number of shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, which a record holder of the same number of shares of Common Stock or Series C Convertible Preferred Stock, as the case may be, for which this Warrant is exercisable immediately prior to the occurrence of such event would own or be entitled to receive after the happening of such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination. If any event requiring an adjustment under this paragraph occurs during the period that an Exercise Price is used in any calculation hereunder, then in such calculation such Exercise Price shall be adjusted appropriately to reflect such event.

3. REPRESENTATIONS AND WARRANTES OF HOLDER. The Holder hereby represents and warrants to the Company that:

(a) Holder acknowledges that this Warrant is issued to the Holder in reliance upon the Holder's representation to the Company that this Warrant will be acquired for investment for the Holder's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that such Holder has no present intention of selling, granting any participation in, or otherwise distributing the same. Holder further represents that the Holder does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to this Warrant.

(b) Holder is an investor in securities of companies in the development stage and acknowledges that it, he or she is able to fend for itself, himself or herself, can bear the economic risk of its, his or her investment, and has such knowledge and experience in financial or business matters that it, he or she is capable of evaluating the merits and risks of the investment in this Warrant. Holder also represents it, he or she has not been organized solely for the purpose of acquiring this Warrant.

(c) Holder is an "accredited investor" within the meaning of Rule 501 of Regulation D, as presently in effect, as promulgated by the Securities and Exchange Commission (the "SEC") under the Securities Act.

(d) Holder understands that this Warrant is characterized as a "restricted security" under the federal securities laws inasmuch as it is being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, Holder represents that it is familiar with Rule 144 as promulgated by the SEC under the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

4. FUNDAMENTAL TRANSACTIONS.

(a) Fundamental Transactions. Prior to the consummation of each Fundamental Transaction pursuant to which holders of shares of Common Stock or Series C Convertible Preferred Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock or Series C Convertible Preferred Stock (a "***Corporate Event***"), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon an exercise of this Warrant at any time after the consummation of the applicable Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock or Series C Convertible Preferred Stock (or other securities, cash, assets or other property) issuable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of the applicable Fundamental Transaction had this Warrant been exercised immediately prior to the applicable Fundamental Transaction (without regard to any limitations on the exercise of this Warrant). Provision made pursuant to the preceding sentence shall be in a form and substance reasonably satisfactory to the Holder.

(b) Application. The provisions of this Section 4 shall apply similarly and equally to successive Fundamental Transactions and Corporate Events.

5. NONCIRCUMVENTION. The Company hereby covenants and agrees that the Company will not, by amendment of the Company's certificate of incorporation, the Company's bylaws or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issue or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (i) shall not increase the par value of any shares of Common Stock or Series C Convertible Preferred Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect and (ii) shall take all such actions as may be reasonably necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable shares of Common Stock or Series C Convertible Preferred Stock upon the exercise of this Warrant.

6. WARRANT HOLDER NOT DEEMED A STOCKHOLDER. Except as otherwise specifically provided herein, the Holder, solely in its capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in its capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company. Notwithstanding this Section 6, the Company shall provide the Holder with copies of the same notices and other information given to the stockholders of the Company generally, contemporaneously with the giving thereof to the stockholders.

7. REISSUANCE OF WARRANTS.

(a) Transfer of Warrant. If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company, whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 7(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 7(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.

(b) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant (as to which a written certification and the indemnification contemplated below shall suffice as such evidence), and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder satisfactory to the Company and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 7(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(c) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 7(d)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, no warrants for fractional shares of Common Stock or Series C Convertible Preferred Stock shall be given.

(d) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Sections 7(a) or 7(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock or Series C Convertible Preferred Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.

8. NOTICES. Except as may be otherwise provided herein, all notices, requests, waivers and other communications made pursuant to this Warrant shall be in writing to the addresses set forth on the signature pages hereof and shall be deemed effectively given: (i) upon personal delivery to the party to be notified, (ii) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient; if not, then on the next business day, (iii) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one (1) day after deposit with an internationally recognized overnight courier, specifying next day delivery, with written verification of receipt.

9. NOTICES OF CERTAIN CORPORATE ACTIONS . The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant, including in reasonable detail a description of such action and the reason therefor. Without limiting the generality of the foregoing, the Company will give written notice to the Holder (i) immediately upon each adjustment of the Exercise Price and the number of Warrant Shares, setting forth in reasonable detail, and certifying, the calculation of such adjustment(s) and (ii) at least fifteen (15) days prior to the date on which the Company closes its books or takes a record (A) with respect to any dividend or distribution upon the shares of Common Stock or Series C Convertible Preferred Stock, (B) with respect to any grants, issuances or sales of any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property to holders of shares of Common Stock or Series C Convertible Preferred Stock or (C) for determining rights to vote with respect to any Fundamental Transaction, dissolution or liquidation, provided in each case that such information shall be made known to the public prior to or in conjunction with such notice being provided to the Holder and (iii) at least ten (10) Business Days prior to the consummation of any Fundamental Transaction.

10. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holder. No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

11. SEVERABILITY. If any provision of this Warrant is prohibited by law or otherwise determined to be invalid or unenforceable by a court of competent jurisdiction, the provision that would otherwise be prohibited, invalid or unenforceable shall be deemed amended to apply to the broadest extent that it would be valid and enforceable, and the invalidity or unenforceability of such provision shall not affect the validity of the remaining provisions of this Warrant so long as this Warrant as so modified continues to express, without material change, the original intentions of the parties as to the subject matter hereof and the prohibited nature, invalidity or unenforceability of the provision(s) in question does not substantially impair the respective expectations or reciprocal obligations of the parties or the practical realization of the benefits that would otherwise be conferred upon the parties. The parties will endeavor in good faith negotiations to replace the prohibited, invalid or unenforceable provision(s) with a valid provision(s), the effect of which comes as close as possible to that of the prohibited, invalid or unenforceable provision(s).

12. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York.

13. REMEDIES, CHARACTERIZATION, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, exercises and the like (and the computation thereof) shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the holder of this Warrant shall be entitled, in addition to all other available remedies, to an injunction restraining any breach, without the necessity of showing economic loss and without any bond or other security being required. The Company shall provide all information and documentation to the Holder that is requested by the Holder to enable the Holder to confirm the Company's compliance with the terms and conditions of this Warrant (including, without limitation, compliance with Section 2 hereof). The issuance of shares and certificates for shares as contemplated hereby upon the exercise of this Warrant shall be made without charge to the Holder or such shares for any issuance tax or other costs in respect thereof, provided that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than the Holder or its agent on its behalf.

14. TRANSFER. This Warrant may not be offered for sale, sold, transferred or assigned by the Holder except in a manner consistent with the restrictive legend on the first page of this Warrant; provided, however, that no such assignment shall relieve the Holder of its obligations hereunder if such assignee fails to perform such obligations.

15. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "***Affiliate***" means any person or entity that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a person or entity, as such terms are used in and construed under Rule 144 under the Securities Act. With respect to a Holder, any investment fund or managed account that is managed on a discretionary basis by the same investment manager as such Holder will be deemed to be an Affiliate of such Holder.

(b) "***Business Day***" means any day other than Saturday, Sunday or other day on which commercial banks in the city of New York, New York are authorized or required by law to remain closed.

(c) "***Common Stock***" means the common stock of the Company.

(d) "***Common Stock Equivalent***" means any Convertible Security or warrant, Option or other right to subscribe for or purchase any share of Common Stock, Series C Convertible Preferred Stock or any Convertible Security.

(e) "***Convertible Securities***" means any stock or other security (other than Options) that is at any time and under any circumstances, directly or indirectly, convertible into, exercisable or exchangeable for, or which otherwise entitles the holder thereof to acquire, any shares of Common Stock or Series C Convertible Preferred Stock.

(f) ***"Equity Financing***" means the issuance and sale by the Company of shares of its Common Stock, Series C Convertible Preferred Stock or Convertible Securities with the principal purpose of raising capital, for cash.

(g) "***Fundamental Transaction***" means that (i) the Company or any of its subsidiaries shall, directly or indirectly, in one or more related transactions, (1) consolidate or merge with or into (whether or not the Company or any of its subsidiaries is the surviving corporation) any other Person, or (2) sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of its respective properties or assets to any other Person, or (3) allow any other Person to make a purchase, tender or exchange offer that is accepted by the holders of more than 50% of the outstanding shares of Voting Stock of the Company (not including any shares of Voting Stock of the Company held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or (4) consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with any other Person whereby such other Person acquires more than 50% of the outstanding shares of Voting Stock of the Company (not including any shares of Voting Stock of the Company held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination), or (5) reorganize, recapitalize or reclassify the Common Stock, or (ii) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") and the rules and regulations promulgated thereunder) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Voting Stock of the Company.

(h) "***Per Share Market Value***" means on any particular date (a) the closing sales price per share of the Common Stock or Series C Convertible Preferred Stock on such date on any registered national securities exchange on which the Common Stock or Series C Convertible Preferred Stock is then listed, or if there is no such closing sales price on such date, then the closing sales price on such exchange on the date nearest preceding such date, or (b) if the Common Stock or Series C Convertible Preferred Stock is not then listed on a registered national securities exchange, the closing sales price for a share of Common Stock or Series C Convertible Preferred Stock in the over-the-counter market, as reported by the OTC Bulletin Board or the OTC Markets Group, Inc. (or similar organization or agency succeeding to its functions of reporting prices) at the close of business on such date, or (c) if the Common Stock is not then reported by the OTC Bulletin Board or the OTC Markets Group, Inc. (or similar organization or agency succeeding to its functions of reporting prices), the fair market value of a share of Common Stock or Series C Convertible Preferred Stock as determined by the Company's board of directors, acting in good faith. In determining the fair market value of any shares of Common Stock or Series C Convertible Preferred Stock no consideration shall be given to any restrictions on transfer of the Common Stock or Series C Convertible Preferred Stock imposed by agreement or by federal or state securities laws, or to the existence or absence of, or any limitations on, voting rights.

(i) "***Options***" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(j) "***Person***" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity or a government or any department or agency thereof.

(k) "***Series C Convertible Preferred Stock***" means the Series C Convertible Preferred Stock of the Company.

(l) "***Voting Stock***" of a Person means capital stock of such Person of the class or classes pursuant to which the holders thereof have the general voting power to elect, or the general power to appoint, at least a majority of the board of directors, managers or trustees of such Person (irrespective of whether or not at the time capital stock of any other class or classes shall have or might have voting power by reason of the happening of any contingency).

[*signature page follows*]

IN WITNESS WHEREOF, the Company and the Holder have caused this Warrant to Purchase Capital Stock to be duly executed as of the Issuance Date set out above.

NANOVIBRONIX, INC.

By: Stephen Brown
Name: Stephen Brown
Title: CFO

Address:

NANOVIBRONIX, INC.
525 EXECUTIVE BOULEVARD
ELMSFORD NY 10523

[_____]

By: _____
Name:
Title:

Address: _____

EXHIBIT A

EXERCISE NOTICE

TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS WARRANT TO PURCHASE CAPITAL STOCK

NANOVIBRONIX, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock or Series C Convertible Preferred Stock ("***Warrant Shares***") of NanoVibronix, Inc., a Delaware corporation (the "***Company***"), evidenced by Warrant No. _____ (the "***Warrant***"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1 . Payment of Exercise Price. The Holder shall pay the Aggregate Exercise Price in the sum of $_____ to the Company in accordance with the terms of the Warrant.

2 . Delivery of Warrant Shares. The Company shall deliver to Holder, or its designee or agent as specified below, _____ Shares of Common Stock and _____ shares of Series C Convertible Preferred Stock in accordance with the terms of the Warrant. Delivery shall be made to Holder, or for its benefit, to the following address:

_____

_____

_____

_____

Date: _____ __, _____

_____

Name of Registered Holder

By: _____

Name:

Title:

EXHIBIT 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of NanoVibronix, Inc. on Form S-3 (File No. 333-229106) of our report dated April 15, 2019, with respect to our audit of the consolidated financial statements of NanoVibronix,Inc. as of December 31, 2018 and for the year then ended, which report is included in this Annual Report on Form 10-K of NanoVibronix, Inc. for the year ended December 31, 2018.

/s/ Marcum llp

Marcum llp
New York, NY
April 15, 2019

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (NO. 333-205577) pertaining to the Stock Option Plan of NanoVibronix, Inc. of our report dated March 29, 2018 with respect to the consolidated financial statements of NanoVibronix, Inc. and its subsidiary as of December 31, 2017 and for the year then ended, included in the Annual Report on Form 10-K for the year ended December 31, 2018.

Tel-Aviv, Israel
April 15, 2019

Kost Forer Gabbay and Kasierer
A member of Ernst & Young Global

EXHIBIT 31.1

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

I, Brian Murphy, certify that:

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

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

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

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

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

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

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

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

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

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

Date: April 15, 2019

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

EXHIBIT 31.2

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

I, Stephen Brown, certify that:

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

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

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

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

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

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

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

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

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

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

Date: April 15, 2019

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

EXHIBIT 32.1

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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the year ended December 31, 2018 of NanoVibronix, Inc. (the "Company"). I, Brian Murphy, the Chief Executive Officer of the Company, certify that, based on my knowledge:

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

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

Date: April 15, 2019

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

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

EXHIBIT 32.2

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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the year ended December 31, 2018 of NanoVibronix, Inc. (the "Company"). I, Stephen Brown, the Chief Financial Officer of the Company, certify that, based on my knowledge:

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

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

Date: April 15, 2019

By: /s/ Stephen Brown
Name: Stephen Brown
Title: Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer)

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