UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

FORM 10-K/A
(Amendment No. 1)

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

For the fiscal year ended: **December 31, 2016**

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)
9 Derech Hashalom Street Nesher, Israel	**36651**
(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: None

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

Common Stock, par value $0.001 per share

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer (Do not check if a smaller reporting company)	☐	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 30, 2016, 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 $10.8 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 March 31, 2017 was 2,632,710 shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

NanoVibronix, Inc., (the "Company") is filing this Amendment No. 1 on Form 10-K/A ("Amendment No. 1") to amend its Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the Securities and Exchange Commission, on March 31, 2017 (the "Original Filing"). The Company is filing this Amendment No. 1 to (i) amend the text of Exhibit 31.1 and Exhibit 31.2 and (ii) correct non-material typographical errors in our Consolidated Statements of Comprehensive Loss.

Other than the revisions of the disclosures as discussed above and expressly set forth herein, this Amendment No. 1 speaks as of the filing date of the Original Filing and does not reflect any events that may have occurred subsequent to such date.

NANOVIBRONIX, INC.

TABLE OF CONTENTS

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 timing of clinical studies and eventual U.S. Food and Drug Administration approval of WoundShield™ and our other 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 wound healing and pain therapy and can be administered at home, without the assistance of medical professionals. Our primary products currently consist of:

- 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;

- PainShield™, a disposable 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

- 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.

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 increase antibiotic efficacy. 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 of America ("U.S." or "United States") by the U.S. Food and Drug Administration and all three of our products have CE Mark approval in the European Union, a Canadian medical device license 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 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 physician or a physical therapist. If U.S. Food and Drug Administration clearance is obtained, we anticipate that WoundShield will require a prescription from a licensed physician in the United States. UroShield will also need a prescription if U.S. Food and Drug Administration clearance is obtained. 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 them, PainShield, UroShield and WoundShield are eligible for sale without a prescription.

In addition to the need to obtain regulatory approvals, we anticipate that sales volumes and prices of our WoundShield and PainShield products will depend in large part on the availability of insurance coverage and reimbursement for self-administered use from third party payers. Third party payers include governmental programs such as Medicare and Medicaid in the U.S., private insurance plans and workers' compensation plans. We do not currently have reimbursement codes for self-administered use or clinical 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., Current Procedural Terminology codes or "CPT codes") for clinical use only, but do not have such reimbursement codes for self-administered use of the product, although the product is marketed and sold for such use. With respect to UroShield, which will 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 self-administered and clinical use of our products in the markets in which we have regulatory authority to sell such products, however, there is no guarantee that we will be successful in obtaining such codes quickly, or at all.

We are currently conducting a double blind clinical trial for UroShield in the U.S. in order to obtain 510(k) clearance from the U.S. Food and Drug Administration. In addition, we are currently ramping up our marketing efforts in North America with respect to PainShield. We anticipate that these efforts will include recruiting indirect sales personnel and representatives, making in-office calls to physicians and attending trade shows and conferences. We have also identified a market for PainShield in the professional sports industry where in many cases reimbursement is either available from sports organizations or by self-pay from wealthy sports figures. In order to pursue this market we are exhibiting at sports trainers meetings and advertising in their media. The PainShield device is offered for sale to practitioners with a pre-formatted rental program at their discretion under a program which was implemented in January 2017. The program will provide for an extension of treatment for patients who may benefit from such therapies. The PainShield product was modified and enhanced through various accessories which allow its use within the equine community. This market is currently being pursued through prominent equine clinicians and independent sales representatives. Early adopters in the use of PainShield in this area have reported positive results. We believe there is an attractive opportunity in this segment due to the lack of an expectation for reimbursement and the opportunity to sell at a premium price point.

Ultrasound Technology and Our Products

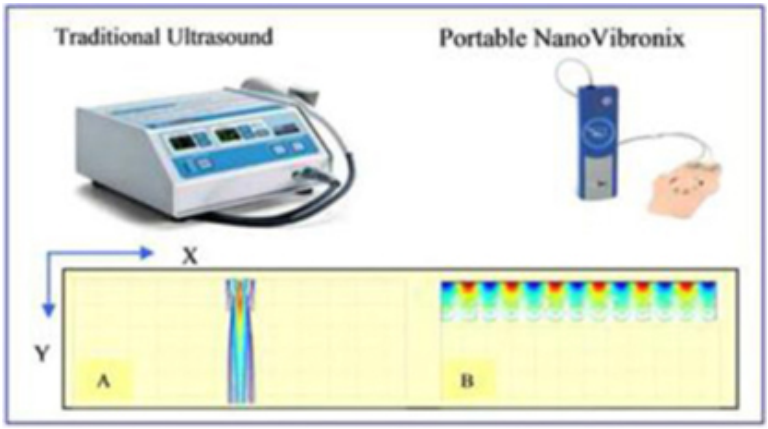
As noted above, our primary products are based on the use of low frequency ultrasound, which delivers energy through mechanical vibrations in the form of sound waves. Ultrasound has long been used in physical therapy, physical medicine, rehabilitation and sports medicine. Moreover, there is a growing body of research that supports the positive biological effects of ultrasound. A 2002 study ago indicates that low frequency ultrasound increases nerve regeneration (Crisci AR, Ferreira AL, “Low-intensity pulsed ultrasound accelerates the regeneration of the sciatic nerve after neurotomy in rats”, Ultrasound Med. Biol. 2002 October; 28(10):1335-41). According to Atland, et. al., low frequency ultrasound also has important therapeutic metabolic effects (Altland OD, Dalecki D, Suchkova VN, Francis CW, “Low-intensity ultrasound increases endothelial cell nitric oxide synthase activity and nitric oxide synthesis”, J. Thromb. Haemost. 2004 April; 2(4):637-43). In addition, there is evidence that ultrasound increases the healing of fractures (Warden SJ, Favaloro JM, Bennell KL, McMeeken JM, Ng KW, Zajac JD, Wark JD, “Low-intensity pulsed ultrasound stimulates the bone-forming response in UMR-106 cells”, Biochem. Biophys. Res. Commun. 2001 August 24; 286(3):443-50 and Warden SJ, Bennell KL, McMeeken JM, Wark JD, “Acceleration of fresh fracture repair using the sonic accelerated fracture healing system (SAFHS)”, Calcif. Tissue Int. 2000 February; 66(2):157-63).

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 causes 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. 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 the delivery of ultrasound through our portable devices is more effective than existing 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 they 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. However, we understand 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 (see the diagram below), that the use of transmission gel is still required and that the transducer thickness is significantly greater than ours (approximately 1.5cm). 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 a small ultrasound device showed positive results in the treatment of venous ulcers, a type of chronic wound. This product is sold under the name of SAM® Sport4 by a company called Zetroz Systems LLC, aka Zetroz, Inc.



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 blood supply (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 (Marvin A., " Nitric Oxide is released into circulation with whole-body, periodic acceleration", Chest 2005;127;30-39).

We believe that the WoundShield Micro Therapy is the first patch device that provides micro vibrations (hertz range vibrations) to the healthy tissue adjacent to the wound in order to stimulate these biological effects, which we believe will lead to faster healing.

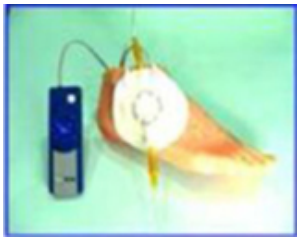
Urinary catheter usage is associated with pain and discomfort caused by the friction between the catheter surface and the urethral tissue. Generally, this friction is treated by applying lubricating gels and low friction catheter coatings. These methods are effective for a short term during the catheter 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 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.

Our Products

WoundShield®

Our WoundShield product 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).

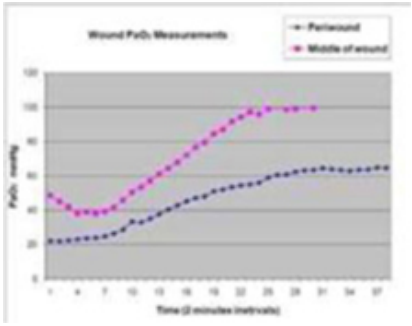


Picture of WoundShield Driver and Instillation Patch

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.

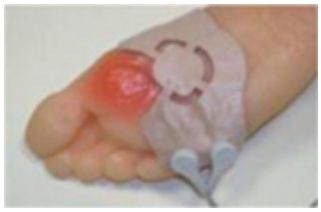
This device has been found to have a positive effect on the epithelialization (healing by the growth of epithelial cells) of diabetic wounds, as well as on the stimulation of the precursors of dermal and epidermal (skin) growth. As such, it is a useful adjunct to wound care by increasing dermal and epidermal 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) (Gasser P, Study Report delivered by BIO-EC Microbiology Laboratory, Dec 2007, which we ordered, paid for, and provided devices for; Rosenblum J, "Surface Acoustic Wave Patch Diathermy Generates Healing In Hard To Heal Wounds," European Wound Management Association 2011, for which we supplied devices but had no further involvement). In 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 and we believe that its performance would exceed the performance of the other ultrasound technologies. 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. Based upon the results of this trial, we are planning a series of clinical trials with an end point claim that our WoundShield product enhances perfusion in chronic wounds.

WoundShield Micro Therapy



WoundShield Micro Therapy Patch placed next to the wound

The WoundShield Micro Therapy device consists of a small electronic driver and a treatment patch. The patch is placed on the healthy skin next to the wound and the incorporated actuator vibrates in the hertz range and provides gentle vibrations to the surrounding tissue. The novelty of this technology is that the vibration effect is produced due to bending vibrations of the actuator (piezo element) and not by means of a motor. These micro vibrations applied on the skin tissue increase local blood flow, vasodilation **,** nitric oxide production and oxygen delivery to the wound area and stimulate angiogenesis and growth factors that help the healing process.

In October 2014, Rosenblum et.al. published in Wounds Journal a study entitled "Surface Acoustic Wave Patch Therapy Affects Tissue Oxygenation in Ischemic Feet." In this study, the WoundShield Micro Therapy device was found to significantly increase oxygen saturation level in the ischemic tissue in all patients by an average of more than 50%. The rate of the drop off after usage varied, but no patient's value returned to pre-device usage levels.

Market for Wound-Healing Devices

The global wound care device market totaled $24,482.9 million in 2015 and it is expected to grow at a compound annual growth rate ("CAGR") of 6.7% during 2016-2022 (as reported by P&S Global Research in January 2017). According to a report entitled "Advances in Wound Closure Technology" by Frost and Sullivan (2005), approximately 25% of all patients with diabetes develop a foot or leg ulceration at some time during the course of their disease. Approximately 3.5 million individuals globally suffer from diabetes related foot or leg ulcerations each year. In addition, according to the National Hospital Ambulatory Medical Survey (2000-2004), approximately 500,000 patients receive medical treatment annually for burn injuries in the U.S., with the global number estimated at 1 million. 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 and WoundShield Micro Therapy

The market for advanced wound care includes a large 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 advantageous technology. However, 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 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 discussed with respect to our competitors in the paragraph above. However, both of 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 is 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 be able to provide superior wound care therapy 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 five years before this device is available on the market. 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 over twelve companies in the U.S. 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.

We are aware of one product that may be competitive with WoundShield Micro Therapy. The Vibro-Pulse is a large, vibrating surface that is placed under the patient’s limb that provides massaging vibration. It is marketed for the repair and regeneration of soft tissue and vascular structures primarily for stimulating wound healing. We believe that our product has the advantage of being smaller and capable of targeting a specific wound area in comparison to this product. In addition, the WoundShield Micro Therapy’s patch-based configuration allows a longer treatment period without limiting the patient to a stationary position.

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, and obtained Canadian License approval in November 2016, both for use in wound healing.

Following preliminary clinical studies that demonstrated WoundShield’s ability to enhance blood perfusion, in June 2014, we started a clinical trial for WoundShield with an end point of enhanced perfusion in chronic wounds at REX hospital in North Carolina. To date, only two patients have been recruited for this study, therefore we terminated this trial. We have not resumed it at another facility.

WoundShield Micro Therapy is a Class I device that does not require a premarket notification application or U.S. Food and Drug Administration clearance before it can be marketed in the U.S. We have listed it with the U.S. Food and Drug Administration.

Sales and Marketing

We have sold limited numbers of our WoundShield products through our website. We intend to aggressively market WoundShield in Europe and Canada, and pursue the necessary approvals to commence marketing in the United States. Our strategy for selling Woundshield in the U.S. is to find a strategic partner in the wound care market . We are actively pursuing this strategy.

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 had a positive effect on both epitheliazation of diabetic wounds as and stimulating the precursors of dermal and epidermal growth. The duration of the trial was 20 days.
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.

PainShield®

PainShield is an ultrasound diathermy device (diathermy is the production of heat in a part of the body by high-frequency electric currents), consisting of a 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 (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 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.

Market for PainShield

Pain is one of the most common conditions that regularly hinders the quality of life of a vast patient population. Pain-related complaints are the most common reason patients seek treatment from physicians (Prince V, "Pain Management in Patients with Substance-Use Disorders," Pain Management, PSAP-VII, Chronic Illnesses). According to Bonica's Management of Pain (2001), a work considered current in the industry based on available industry data, and 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 25% of the U.S. population, or approximately 75 million people, suffer from chronic pain. We estimate that approximately 150 million individuals globally suffer from chronic 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. 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 is generally not supported by widespread clinical evidence of its efficacy. In addition, 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 selected medical conditions such as relief of pain, muscle spasms and joint contraction. PainShield received CE Mark approval in July 2008 and was also approved for sale by the Israeli Ministry of Health in 2010. We have a Canadian medical device license for PainShield and we are able to sell PainShield in India and Ecuador based on our CE Mark.

In the U.S., 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 and other clinical problems, such as tendonitis, sports injuries, pelvic pain and neurologic pain and we have sold approximately 1,500 units and 8,000 treatment patches since its introduction. We have entered into distribution agreements in North America, Europe, Asia and the Middle East for the distribution of PainShield. We intend to seek additional distribution opportunities in Europe, East Asia and South America. In addition, we sell PainShield directly to patients through our website. We are currently ramping up our marketing efforts in North America. 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 also identified a market for PainShield in the professional sports industry where in many cases reimbursement is either available from sports organizations or by self pay from wealthy sports figures. In order to pursue this market we are exhibiting at sports trainers meetings and advertising in their media.

Research

A double blind randomized control trial of a Surface Acoustic Wave Patch device is currently enrolling for the treatment of trigeminal neuralgia. This is a crossover study for the group that receives the sham device. Subjects will be monitored for subjective criteria of pain and quality of life, as well as objective measurement of analgesic usage. This study’s target enrollment is expected to be 60 patients. Enrollment began in November 2016. The study should be finalized by the fall of 2017.

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

Clinical Trials

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

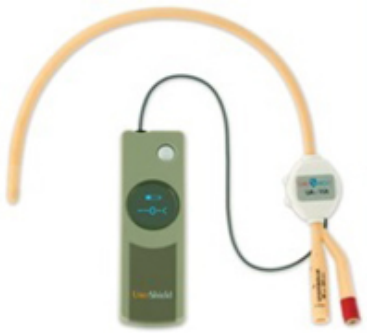
Purpose	Doctor/Location	Time, subjects	Objectives	Results
A sound solution for Trigerminal Neuralgia Physician initiated	Dr. Ch. Adahan Shiba medical Center	2009 15 patients	· Reduction in pain · Reduction in disability · Improvement of function and quality of life · Accelerating of healing	73% of the subjects experienced complete or near complete relief.
Randomized control trial examining the efficacy of low intensity low frequency Surface Acoustic wave ultrasound in trigerminal neuralgia pain For Ph.D., Funded by Israeli Ministry of Health	Dr. M. Zwecker Chaim Sheba Medical Center, Tel Hashomer, Israel	2012-2012 19 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 trigerminal neuralgia disease.
Treating Rutgers university athletic injuries with bandaid sized ultrasound unit PainShield	R. Monaco, G. Sherman, Rutgers University Athletic, Rutgers, New Jersey	2011 40 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	Preliminary results: Active group: 70% had improvement, 30% no change Sham group: 70% no change, 30% had improvement This is a really good 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.

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

Trial	Place	Start Date/Timing	Objectives
PainShield for Trigeminal Neuralgia 80 patient trial	To be determined	To be determined	Safety and Efficacy of PainShield in Trigeminal Neuralgia
PainShield for Pelvic Pain 200 patient trial	To be determined	To be determined	Safety and Efficacy of PainShield in Chronic Pelvic Pain

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 UroShield is 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

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, 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 (Tenke P, "The effectiveness of acoustic energy induced by UroShield in the prevention of bacteriuria and the reduction of patients' complaints related to long-term indwelling urinary catheters," 26th Annual Congress of the European Association of Urology (EAU) Congress, Vienna, March 2011; we supplied devices for this study and paid for electron microscopy analysis, but had no further involvement with it).

- **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. 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 bilofilm 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 bacteruria, as compared to one in the active group. In a third trial, a physician-sponsored open label trial, ten 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

According to State of the Globe: Catheterizations Continue to Cultivate Urinary Infections – Journal of Global Infectious Diseases May-Aug 2010 , over 55 million indwelling urinary catheters are consumed annually worldwide. 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 U.S. 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 catheter acquired urinary tract infection, 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)).

Every day approximately five percent of catheterized patients develop bacteriuria and up to 50% of patients develop bacteriuria over one week. Virtually all patients requiring indwelling urinary catheters for longer than a month become bacteriuric. Most episodes of bacteriuria associated with short-term catheters are asymptomatic. As the catheter remains in place the bacteriuria becomes complex, polymicrobial, and dynamic.[70] Escherichia coli is the dominant pathogen accounting for most urinary tract infections ("UTI") followed by S. epidermidis, S. saprophyticus, and Enterococcus species. Less common organisms, such as Gardnerella vaginalis, Mycoplasma species, and Ureaplasma urealyticum may also infect patients with intermittent or indwelling catheters. Constitutional symptoms suggestive of UTI occur in a third of catheterized patients, though less than five percent develop bacteremia (the presence of bacteria in the blood).

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 bacteruria 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 achieve its anticipated catheter market share due to a number of factors, including, but not limited to, an inability to obtain approval of the U.S. Food and Drug Administration and failure to be adopted by health care practitioners and facilities because of its status as a new product in the market, without an established niche.

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.

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 U.S., 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) approval 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. A more robust study is currently underway which is intended to enroll 63 patients in a randomized controlled trial. This ongoing study has been approved by the institutional review board ("IRB") and is currently enrolling patients within two nursing home in upstate New York. The trial is a double blind, randomized control trial with a projected endpoint of pain reduction and reduction of bacterial colonization on the urinary catheter. We intend to submit for approval to the U.S. Food and Drug Administration after completion of this ongoing study.

Sales and Marketing

We believe the business opportunity for Uroshield is in the hundreds of millions in USD. To that end we are exploring sales distribution models in the U.S. through a distributor network and direct sales. We are currently identifying distributors through several vehicles, including our sales staff, commissionable representation, and independent contractors. The clinical study underway may provide the evidence to prevent, and treat the formation of biofilm colonies which we believe will result in significant improved patient outcomes, and the savings to the healthcare system from treating patients with UTI's and the re-hospitalization of outpatients.

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 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 40 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 markedly 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 bacteruria Physician initiated	Prof. P.Tenke, Hungary	2010-2011 26 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.

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

Third Party Reimbursement

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans and workers' compensation plans. These third party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been approved or cleared by the 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 U.S., some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use products, including ours.

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

The initial phase of establishing a professional billing code for a medical service typically includes applying for a Current Procedural Terminology, or CPT, Category III code. This is a tracking code without relative value assigned that allows third party payers to identify and monitor the service as well as establish value if deemed medically necessary. The process includes CPT application submission, clinical discussion with Medical Professional Society CPT advisors as well as American Medical Association CPT Editorial Panel review. A new CPT Category III code will be assigned if the American Medical Association CPT Editorial Panel committee deems it meets the applicable criteria and is appropriate.

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

We believe that the overall escalating costs of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. In addition, recent healthcare reform measures, as well as legislative and regulatory initiatives at the federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third party payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

The Diagnosis Related Group System, or DRG, is the system of reimbursement that is used in the United States for hospitalized patients as well as patients who are cared for in skilled nursing facilities and long term care facilities. These facilities are not subject to the same reimbursement codes as described above. In the DRG system, each patient admitted to the hospital or facility is assigned a code based on his or her diagnosis. That code is known to be associated with an average hospital stay and the health care facility is reimbursed for the amount of days as defined by the DRG code, regardless of how many days the patient is in the facility. This system gives a strong incentive for these health care facilities to deliver efficient care and to complete the needed treatment as quickly as possible. For example, if the patient has a wound that requires healing before discharge and they succeed in treating the wound in less hospital days than allowed by the DRG code for this diagnosis, the facility will be rewarded by being paid more for more days than the patient was actually in the hospital for. Conversely, if the treatment takes longer, the facility would actually lose income, as they will be paid for the DRG code only. This system serves as a stimulus for these facilities to purchase and utilize devices and technologies that allow more efficient therapy.

PainShield. PainShield is presently reimbursed in the U.S. by many private insurers 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. 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 purchased by a clinic, PainShield is typically purchased by the clinic that then bills the existing reimbursement codes. PainShield is not 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.

WoundShield We believe that the initial usage of these products will be in the hospital setting. Reimbursement in the hospital setting is governed by the diagnosis-related group system, which does not require specific reimbursement codes. In parallel to introducing these devices to hospitals, we intend to apply for reimbursement codes for outpatient use. Although obtaining these codes can take two to five 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.

UroShield. We expect these products to be used in hospital settings and therefore reimbursed under the diagnosis-related group reimbursement system. In addition, 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.

New Products Under Development

Renooskin

We have started developing a device for the facial rejuvenation market called Renooskin in 2016. Previous in vitro clinical 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. The Company has developed a head band like applicator for the SAW treatment and is in the process of arranging for a pilot trial with a cosmetic dermatologist and/or plastic surgeon. The Company believes that, subject to proof of efficacy of the Renooskin and receiving regulatory approval, the device can be sold in a non-reimbursement market since cosmetic devices are private pay. We expect the first articles to test in the second quarter of 2017.

Lungshield

A pilot study, adapting the UroShield technology to endotracheal tubes, is currently underway at Shaare Zedek Medical Center, under Reuveen Friedmann as the Principle Investigator. 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. The interim results of the study are likely to be published prior to the completion of the study. The targeted completion for the study is fall 2017.

Research and Development Expenses

During the years ended December 31, 2016 and 2015 we spent approximately $584,000 and 399,000, respectively, on research and development activities. None of the cost of such activities is borne directly by our customers.

Intellectual Property

Patents

We believe that our patent portfolio provides us with sufficient protection of our patentable intellectual property. We have six patents in the U.S. and three filed applications. 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. 7,892,191 (having the following foreign counter-parts: Russia 2419395 and Australia 2005331251), "Nanovibration coating process for medical devices using multi vibration modes of a thin piezo element" and granted U.S Patent 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. These U.S. patents expire on December 19, 2023 and February 26, 2027, respectively. U.S. Patent Application No. 11/710,615 (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.

We also license three patents pursuant to a license agreement with Piezo-Top Ltd and PMG Medica Ltd., U.S. Patent No. 6,454,716 B1, "A system and method for detection of fetal heartbeat," and U.S. Patent No. 6,964,640 B2, "A system and method for detection of motion," which incorporate certain technology related to biofilm prevention for medical purposes, including biofilm prevention in indwelling catheters, biofilm prevention in dialysis and respiratory assist devices and is based on unique configuration of piezoelectric elements in cooperative configuration with series of oscillators that are able to transmit and receive ultrasonic waves simultaneously. 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. U.S. Patent No. 7,431,892 B2, "Apparatus for sterilizing a liquid with focused acoustic standing waves," relates to our original work introducing multiple modes of power into an ultrasonic transducer for purpose of sterilizing liquids. This patent has been the genesis of the more practical patents described above. This patent expires on July 29, 2024. See "—License Agreements" below.

Just recently, the Company has been granted a patent by the United States Patent and Trademark Office entitled, " *System and Method for Surface Acoustic Wave Treatment of Skin*," with a term through 2033, which does not include regulatory extensions.

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 system and method for surface acoustic wave treatment.

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 U.S.: NanoVibronix®, WoundShield®, PainShield®, UroShield® and "Curing though prevention"®. 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.

License Agreement

In October 2003, we entered into a license agreement with Piezo-Top Ltd and PMG Medica Ltd, pursuant to which we were granted an exclusive, worldwide license for the duration of the patent life of U.S. Patent No. 6,454,716 B1, U.S. Patent No. 6,964,640 B2 and U.S. Patent No. 7,431,892 B2 (see "—Patents" above). In exchange for the license, we paid Piezo-Top Ltd and PMG Medica Ltd payments of (i) $5,000 each after the first round of investment in us, (ii) $7,500 each after the second round of investment in us, and (iii) $25,000 each after either the third round of investment, the purchase of at least 40% of our stock or our initial public offering. We have made all three of the required payments under this agreement.

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 U.S. Before and after approval or clearance in the U.S., our 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. WoundShield and Micro Therapy are Class I devices and will not need a premarket notification application or U.S. Food and Drug Administration clearance before they can be marketed in the U.S. However, we have listed them with the U.S. Food and Drug Administration.

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

In the U.S., 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;
- Class II: special controls, pre-market notification (510(k)), specific controls such as performance standards, patient registries and post-market surveillance and additional controls such as labeling and adherence to quality system regulations; and
- Class III: special controls and approval of a pre-market approval, 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. WoundShield and Micro Therapy are classified as Class I medical devices, and do not require any additional authorization from the U.S. Food and Drug Administration. However, we have listed them with the U.S. Food and Drug Administration.

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.

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

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 pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the 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 guaranty 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 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. Current good manufacturing practices 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 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, Canada 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 Canada medical device license for PainShield, 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. Anti-Kickback and False Claims Laws

In the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the U.S. Food and Drug Administration as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. Other provisions of federal and state laws provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, certain states have implemented regulations requiring medical device and pharmaceutical companies to report all gifts and payments over $50 to medical practitioners. This requirement does not apply to instances involving clinical trials.

Customers

We currently sell our products both through our website and distribution agreements, with approximately 30% of our sales coming through distributors in 2016. We have exclusive distribution agreements for our products with medical product distributors based in the U.S. (for PainShield for abdominal and pelvic pain since 2012, Italy (since 2013), India (since 2012), United Kingdom (since 2010) and Israel (since 2012).

We are currently in discussions with a number of distribution companies in Europe, Asia, and Latin America. Our current agreements stipulate that, while we are responsible for training, providing marketing guidance, marketing materials, and technical guidance, distributors will be responsible for carrying out local marketing activities and sales. 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 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., Rotel Product Engineering Ltd. and Amit Industries L.T.D (AmiCell). We do not have written agreements with any of these suppliers, but we believe anyone could be easily replaced if necessary.

Employees

As of December 31, 2016, we had eight full-time employees and two contract employees. There are no part-time employees. Our employees are not party to any collective bargaining agreements. We consider our relations with our employees to be good. We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below together with the other information set forth in this Annual Report on Form 10-K, before purchasing our securities which could materially affect our business, financial condition and future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and operating results. If any of the following risks are realized, our financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline.

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, 2016, we had a net loss of $2,831,000, with revenues of $229,000. As of December 31, 2016, we had an accumulated deficit of $22,576,000 and a total stockholders' deficit of $2,499,000. 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 of PainShield, which will require costly 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.

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. We will seek to obtain additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. These financings could result in substantial dilution to the holders of our common stock, or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations 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. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

A variety of factors could impact 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.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line through acquisitions 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 U.S. 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 U.S., 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, foreign 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 entitlement 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. 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 U.S. 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 or our collaborators' 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.

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

As a small company with eight full-time employees and three 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.

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 U.S. 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 U.S. 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 U.S. 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 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 U.S. 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. 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 claims, 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 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 U.S. and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in 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;
- injunctions; and
- criminal prosecutions.

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

- testing;
- manufacturing;
- quality control;
- 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 U.S. 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 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 healthcare reform in the U.S. may adversely affect our business and financial results.

On March 23, 2010, President Obama signed into law major healthcare reform legislation under the Patient Protection and Affordable Care Act of 2010, or the PPACA, which was modified on March 30, 2010 by the enactment of the Health Care and Education Reconciliation Act of 2010. Under the PPACA, it is expected that expanded healthcare coverage will be made available to an additional 30 million Americans. The increased costs to the U.S. government from the PPACA are expected to be funded through a combination of payment reductions for providers over time and several new taxes. We will also need to assess whether we are subject to it with respect to other products when they are approved for sale in the U.S. The PPACA also provides for the establishment of an Independent Medicare Advisory Board that could recommend changes in payment for physicians under certain circumstances beginning in 2014. In addition, the PPACA authorizes certain voluntary demonstration projects beginning no later than 2013 around development of bundling payments for acute, inpatient hospital services, physician services, and post-acute services for episodes of hospital care. The PPACA increases fraud and abuse penalties and expands the scope and reach of the Federal Civil False Claims Act and government enforcement tools, which may adversely impact healthcare companies.

If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state laws, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other federal healthcare program. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the federal Anti-Kickback Statute, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by federal healthcare programs, but instead apply regardless of the source of payment. Violations of the federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in federal healthcare programs.

All of our financial relationships with healthcare providers and others who provide products or services to federal healthcare program beneficiaries are potentially governed by the federal Anti-Kickback Statute and similar state laws. We believe our operations are in compliance with the federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Our Organization and Our Securities

We are currently controlled by our executive officers, directors and principal stockholders, and our executive officers, directors and principal stockholders have significant influence regarding all matters submitted to our stockholders for approval.

As of March 31, 2017, our directors, executive officers and 5% or greater stockholders beneficially owned approximately 70.8% of our voting capital stock. As a result, if these stockholders were to choose to act together, they would be able to exercise significant influence with respect to all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will exercise significant influence with respect to the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, and might affect the prevailing market price for 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 "Item 1A. 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.

Future sales of our common stock, 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 options and 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, option holders and warrant holders 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.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management may be required to devote substantial time to compliance matters.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission and The Nasdaq Stock Market, have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel may need to devote a substantial amount of time to these compliance matters. Moreover, these rules and regulations may increase our legal and financial compliance costs and may make some activities more time consuming and costly.

Changes in the laws and regulations affecting public companies will result in increased costs to us as we respond to their requirements. These laws and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

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 will continue to be deemed an emerging growth company until the earliest of (i) the last day of the fiscal year during which we had total annual gross revenues of $1 billion (as indexed for inflation); (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of common stock in an offering registered under the Securities Act of 1933, as amended; (iii) the date on which we have, during the previous 3-year period, issued more than $1 billion in non-convertible debt; or (iv) 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 the auditor's attestation on internal control over financial reporting that would otherwise be required by the Sarbanes-Oxley Act, as described above 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, we received grants of $436,815 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.

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 are located in Israel and most of our officers, employees and directors 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 winter of 2012, Israel was engaged in an armed conflict with Hamas, a militia group and political party operating in the Gaza Strip. This conflict involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. Recent political uprisings and civil resistance demonstrations 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, or the Arab Spring in general, will develop and how it will affect the political and security situation in the Middle East. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have 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. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy generally 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.

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. 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 U.S. to enforce any judgments obtained against us or any of our directors or officers.

Almost all of our assets are located outside the U.S., although we do maintain a permanent place of business within the U.S. In addition, all of our officers and some of our directors are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the U.S. 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 U.S. or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the U.S. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease an office and manufacturing facility in Nesher, Israel and an office in Elmsford, New York. Our lease for the facility in Nesher expires June 30, 2017. The space is approximately 230 square meters. We pay approximately $2,500 per month under our lease. We also use a small office in Elmsford, New York. The use of this space is included in a services agreement pursuant to which we pay $4,000 per month for, among other services, processing products for shipping, customer service, payment processing and maintenance of certain records. 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 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 following table sets forth, for the periods indicated, the high and low bid prices of our common stock as reported on the OTCQB. The quotations reflect inter-dealer prices, without retail markup, markdown, or commissions, and may not represent actual transactions.

	High	Low
2016		
First Quarter	$ 4.95	$ 4.15
Second Quarter	$ 5.50	$ 4.75
Third Quarter	$ 5.56	$ 5.20
Fourth Quarter	$ 7.00	$ 5.50
2015		
Second Quarter (from April 10, 2015 to June 30, 2015)	$ 4.00	$ 3.50
Third Quarter	$ 4.65	$ 3.50
Fourth Quarter	$ 4.86	$ 4.70

As of March 31, 2017, there were approximately 131 holders of record of our common stock.

As of March 31, 2017, we had a total of 1,951,261 shares of our series C preferred stock 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 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.

Dividend Policy

In the past, we have not declared or paid cash dividends on our common stock and Series C preferred stock, and we do not intend to pay any cash dividends on our common stock. Rather, we intend to retain future earnings (if any) to fund the operation and expansion of our business and for general corporate purposes. Subject to legal and contractual limits, our board of directors will make any decision as to whether to pay dividends in the future.

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 January 27, 2017, 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 and warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of $6.00 per share, issued in January and February 2015, to extend the expiration date of the warrants for two additional years. Pursuant to the Warrant Amendment, warrants to purchase 266,667 shares of common stock at $3.00 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share were to expire on January 29, 2019, and the warrants to purchase 140,000 shares of common stock at $3.00 per share and warrants to purchase 140,000 shares of common stock at $6.00 per share were to expire on February 10, 2019, and the warrants to purchase 13,333 shares of common stock at $3.00 per share and warrants to purchase 13,333 shares of common stock at $6.00 per share were to expire on February 23, 2019. The exercise price and all other terms of the original warrants remain the same.

Holders of the warrants that entered into the Warrant Amendment with the Company include the following: (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 $3.00 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share, and (ii) Paul Packer and entities controlled by Mr. Packer, a greater than five percent stockholder of the Company, who holds warrants to purchase 66,666 shares of common stock at $3.00 per share and warrants to purchase 66,666 shares of common stock at $6.00 per share.

On March 1 and March 23, 2017, the Company completed bridge financings, pursuant to which the Company received from four accredited investors an aggregate of $350,000 of loans and issued to the investors convertible promissory notes (the "Notes") in an aggregate principal amount of $350,000 and seven-year warrants (the "Warrants") to purchase an aggregate of 140,000 shares of common stock (the "Warrant Shares") at an exercise price of $5.90 per share (the "Exercise Price").

The principal amount and all accrued but unpaid interest on the Notes will become 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, each investor will receive, at the option of the investor, either (a) cash equal to the original principal amount of the 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. If there is a change of control and the Notes have not been previously converted otherwise, the investors may, at their option, (a) receive an amount in cash equal to the sum of the original principal amount of the Notes and interest then accrued and unpaid thereon, or (b) convert the Notes and all accrued and unpaid interest thereon into shares of common stock or Series C Convertible Preferred Stock of the Company immediately prior to the closing of such change of control transaction 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 implied by the exchange ratio set forth in the agreement governing such change of control transaction, 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, 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 the Company's capital stock.

The Warrants are immediately exercisable. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the resale of the Warrant Shares after the six month anniversary of the issuance date of the Warrants. The Exercise Price is adjustable for certain events, such as distribution of stock dividends, stock splits or fundamental transactions including mergers or sales of assets. A holder of the Warrants will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. 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 61 days after such notice to the Company.

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 financial statements have been prepared in U.S. dollars.

The majority of our expenses, financing activities and revenues are denominated and determined in U.S. dollars. We believe that the U.S. dollar is the currency of the primary economic environment in which we operate and expects to continue to operate in the foreseeable future. Thus, the functional and reporting currency of the Company is the U.S. dollar.

The Company's transactions and balances denominated in U.S. dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to U.S. dollars in accordance with the Accounting Standards Board (ASC) 830, "Foreign Currency Matters". All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statements of comprehensive loss as financial income or expenses, 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 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.

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 the Company's consolidated statement of comprehensive loss.

We have early adopted Accounting Standard Update ("ASU") 2016-09, "Compensation - Stock Compensation", in the current 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 the Company's stock options are expected to be outstanding. We currently uses 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 the Company's historical experience and expectation of no future dividend payouts. We have historically not paid cash dividends and has 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

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

We 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.

Convertible promissory notes

We account for our outstanding convertible promissory notes in accordance with ASC 470-20, “Debt with Conversion and Other Options” (“ASC 470-20”) and ASC 815 “Derivatives and Hedging” (“ASC 815”).

In accordance with ASC 470-20 we first allocate the proceeds to freestanding liability instrument (warrants) that are measured at fair value at each reporting date, based on their fair value. The remaining proceeds are allocated among all other freestanding instruments (embedded beneficial conversion feature and convertible debt) based on the relative fair values of the instruments at the time of issuance.

In addition, under the guidelines of ASC 470-20, we measure an embedded beneficial conversion feature on the date of issuance, by allocating a portion of the proceeds equal to the intrinsic value of the feature to additional paid in capital. The intrinsic value of the feature is calculated on the date of issuance using the effective conversion price which results from the allocation of the proceeds between the convertible debt and the embedded derivative component. The intrinsic value is limited to the portion of the proceeds allocated to the convertible debt. We recognize an embedded beneficial conversion feature related to our convertible promissory notes. The beneficial conversion feature is amortized to our consolidated statements of comprehensive loss over the term of the liability.

Warrant liability

The fair value of the liability for our warrants issued to investors in 2013 and 2014 was calculated using the Black-Scholes model. We accounted for these warrants according to the provisions of ASC 815 and, based on the anti-dilution protections contained in the warrants, we classified them as liabilities, measured at fair value for each reporting period until they are exercised or expire, with changes in fair value recognized in our consolidated statement of comprehensive loss as financial income or expense.

Recently issued accounting standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). On July 9, 2015 the FASB voted to approve a one-year delay of the effective date and to permit companies to voluntarily adopt the new standard as of the original effective date. The new standard is effective for reporting periods beginning after December 15, 2018. The standard will supersede existing revenue recognition guidance, including industry-specific guidance, and will provide companies with a single revenue recognition model for recognizing revenue from contracts with customers.

The standard requires revenue to be recognized when promised goods or services are transferred to customers in amounts that reflect the consideration to which the company expects to be entitled in exchange for those goods or services. Adoption of the new rules could affect the timing of revenue recognition for certain transactions. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application.

In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing" ("ASU 2016-10"), which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. The amendment will be effective with ASU 2014-09.

In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients" ("ASU 2016-12"), which amends the guidance in the new revenue standard on collectability, noncash consideration, presentation of sales tax, and transition. The amendments are intended to address implementation issues and provide additional practical expedients to reduce the cost and complexity of applying the new revenue standard. The new standard will be effective with ASU 2014-09.

In December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which clarifies specific aspects of ASU 2014-09, including allowing entities not to make quantitative disclosures about remaining performance obligations in certain cases and requiring entities that use any of the new or previously existing optional exemptions to expand their qualitative disclosures. The new standard also makes twelve other technical corrections and improvements to ASU 2014-09. The new standard will be effective with ASU 2014-09.

We are still in the process of completing its assessment on the impact this guidance will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB ASU 2016-02-Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840. The standard is effective on January 1, 2020, with early adoption permitted. We are currently evaluating the impact of the adoption of this standard on our consolidated financial statements.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting". The update simplifies certain aspects of the accounting for share-based payment transactions, including income taxes, classification of awards and classification in the statement of cash flows and forfeiture rate calculation. The amendments of this ASU are effective for reporting periods beginning after December 15, 2016 for public entities. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted however all of the guidance must be adopted in the same period. We have early adopted Accounting Standard Update ("ASU") 2016-09, "Compensation - Stock Compensation", in the current consolidated financial statements and account for forfeitures as they occur.

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 the Company will continue as a going concern. Since its formation, the Company utilized funds generated from private placement offerings and debt to fund its product development, incurred losses in the amount of $2,831 during the year ended December 31, 2016 and has an accumulated deficit of $22,576 as of December 31, 2016. The recurring losses from operations and current liquidity raise substantial doubt about the Company's ability to continue as a going concern. Continuation of the Company is dependent on obtaining additional financing.

Twelve Months Ended December 31, 2016 Compared to Twelve Months Ended December 31, 2015

Revenues. For the twelve months ended December 31, 2016 and 2015, our revenues were approximately $229,000 and $147,000, respectively, an increase of approximately 55.8%, or $82,000, between the periods. The increase was mainly attributable to increased sales from adding distributors as well as having positive results from our increased marketing campaigns. 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 may fluctuate from period to period and, as we continue to grow our business, growth in 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 forseeable future.

For the twelve months ended December 31, 2016, the percentage of revenues attributable to our products was: PainShield – 90.8% and UroShield – 9.2%. For the twelve months ended December 31, 2015, the percentage of revenues attributable to our products was: PainShield – 96% and UroShield – 4%. For the twelve months ended December 31, 2016 and 2015, the percentage of revenues attributable to our disposable products was 42.5% and 59.9%, respectively. For the twelve months ended December 31, 2016 and 2015, the portion of our revenues that was derived from distributors was 30.3% and 23.2%, respectively.

Gross Profit. For the twelve months ended December 31, 2016, gross profit increased by approximately 43.9%, or $43,000, to approximately $141,000 from approximately $98,000 during the same period in 2015.

Gross profit as a percentage of revenues were approximately 61.6% and 66.6% for the twelve months ended December 31, 2016 and 2015, respectively. The decrease in gross profit as a percentage is mainly due to the increased percentage of distributor sales which typically carry a lower gross profit percentage than our direct to consumer sales, and to a lesser degree, the decreased percentage of revenues attributable to our disposable products which typically have higher margins also contributed to the reduction.

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, 2016 and 2015, research and development expenses were $584,000 and $399,000, respectively, an increase of approximately 46.37%, or $185,000, between the periods. This increase was mainly due to an increased volume of clinical trial costs that took place in 2016 as well as increased development of new products.

Research and development expenses as a percentage of total revenues were approximately 255.0% and 271.4% for the twelve months ended December 31, 2016 and 2015, 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, 2016 and 2015, selling and marketing expenses were approximately $514,000 and $377,000, respectively, an increase of approximately 36.3%, or $137,000, between the periods.

The increase in selling and marketing expenses was mainly due to an increase in selling and marketing activities, particularly increased trade show expenses, new marketing campaigns initiated in 2016 and increased compensation.

Selling and marketing expenses as a percentage of total revenues were approximately 224.5% and 256.5% for the twelve months ended December 31, 2016 and 2015, respectively. The decrease in our percentage was due to the increase in revenues.

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, 2016 and 2015, general and administrative expenses were approximately $1,359,000 and $746,000, respectively, an increase of approximately 82.17%, or $613,000, between the periods.

The increase was mainly attributable to incurring professional fees and other costs associated with becoming a publicly traded company, an increase in executive compensation as we added new management and an increase in stock-based compensation to our management and directors.

General and administrative expenses as a percentage of total revenues were approximately 593.44% and 507.48% for the twelve months ended December 31, 2016 and 2015, respectively. The increase was due to the increase in general and administrative expenses, described above.

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, 2016 and 2015, financial expenses, net were $398,000 and $1,432,000, respectively, a decrease of approximately 72.2%, or $1,034,000, between the periods. The decrease resulted primarily from the lower valuation adjustment of our warrants and amortization of the benefit component of promissory notes

Tax expenses. For the twelve months ended December 31, 2016 and 2015, tax expenses were $117,000 and $28,000 respectively. The tax expense 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 $53,000, or 1.8%, to approximately $2,831,000 for the twelve months ended December 31, 2016 from approximately $2,884,000 during the same period in 2015. The decreased in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

We have incurred losses in the amount of $2,831,000 during the year ended December 31, 2016, and have accumulated negative cash flow from operating activities of $1,533,000 for the year ended December 31, 2016. 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. 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, 2016, and through March 31, 2017, we met our short-term liquidity requirements from our existing cash reserves and bridge financings of $350,000. 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 intend to continue to use our existing cash reserves to meet our short-term liquidity requirements as well as to advance our long-term plans. It is our current belief that if we do not continue to see significant increases in revenues, or if we are unable to raise additional capital at a later time in the current year, we will need to reduce our operating budget as well as sales and marketing expenses which may impair our ability to execute our business objectives. 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, 2016, and we are not aware of any material trends in capital resources that would impact our business.

Twelve Months Ended December 31, 2016 Compared to Twelve Months Ended December 31, 2015

General. As of December 31, 2016, we had cash and cash equivalents of approximately $106,000, compared to approximately $1,614,000 as of December 31, 2015. 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 $1,533,000 for the twelve months ended December 31, 2016 and approximately $1,480,000 for the same period in 2015. The increase in our usage of cash in our operating activities in the amount of $53,000 is mainly attributable to the increase in costs associated with being a publicly traded company, and the increase in research and development and sales and marketing costs described above.

Cash used in our investing activities was approximately $8,000 during the twelve months ended December 31, 2016 and $1,000 during the twelve months ended December 31, 2015.

Cash provided by financing activities was approximately $33,000 from proceeds from the exercise of stock options for the year ended December 31, 2016 compared to $3,005,000 for the twelve months ended December 31, 2015, which derived from issuance of shares of common stock, series C preferred stock and warrants to purchase shares of common stock for aggregate consideration of $3,005,000, which is net of issuance costs of $145,000.

Off Balance Sheet Arrangements

As of December 31, 2016, 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*.**

We conducted an evaluation of the effectiveness of our "disclosure controls and procedures" ("Disclosure Controls"), as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2016, the end of the period covered by this Annual Report on Form 10-K. The Disclosure Controls evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our chief executive officer and chief financial officer have concluded that our Disclosure Controls were effective at the reasonable assurance level as of December 31, 2016.

Management's Report on Internal Control over Financial Reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting 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 over time.

Management, including our chief executive officer and chief financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control—Integrated Framework (2013)*. Based on its assessment and those criteria, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2016.

Changes in Internal Control over Financial Reporting.

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information regarding our executive officers and the members of our board of directors. All directors hold office for one-year terms until the election and qualification of their successors. Officers are elected by the board of directors and serve at the discretion of the board.

Name	Age	Position
Brian Murphy	60	Chief Executive Officer and Director
William Stern, Ph.D.	75	President and Vice Chairman of the Board of Directors
Stephen Brown	60	Chief Financial Officer
Harold Jacob, M.D.	62	Chief Medical Officer and Director
Jona Zumeris, Ph.D.	65	Vice President of Technology and Director
Christopher Fashek	66	Chairman of the Board of Directors
Martin Goldstein, M.D.	48	Director
Michael Ferguson	45	Director
Thomas R. Mika	64	Director

Brian Murphy, Chief Executive Officer and Director. Mr. Murphy has served as our chief executive officer and director since October 2016. Mr. Murphy has over 25 years of senior sales, operations and general management experience in medical device and medical technology companies, including ATI Medical Equipment Corporation, Mountain Medical Equipment Inc. and Healthdyne Technologies Inc. From 2012 to 2016, Mr. Murphy served in various roles at MiMedx Group, Inc., where he initiated and managed the commercial sales and national accounts efforts within the advanced wound care segment. From 2010 to 2012, Mr. Murphy was the Chief Executive Officer of O2 Insights, Inc., a start-up wound care diagnostics company, and led the sale of the company to Systagenix in June 2012. From 2008 to 2010, Mr. Murphy served as vice president of sales for ConvaTec and led the negative pressure wound therapy business. From 1992 to 2008, Mr. Murphy served a total of 17 years at Kinetic Concepts, Inc. (KCI) in various positions overseeing sales, operations and general management. As Vice President, General Manager, Mr. Murphy led a segment of the wound care division's business at KCI from $11 million to over $550 million in annual revenues. Mr. Murphy holds a Bachelor of Arts degree in communications from Southern Illinois University.

William Stern, Ph.D., President and Vice Chairman of the Board of Directors. Dr. Stern has served as our president and vice chairman of the board of directors since October 2016 and, prior to that, as our chief executive officer and director since December 2015. Dr. Stern has served as president of Multigon Industries, Inc., which manufactures non-invasive ultrasound technology that measures blood flow in the brain, since 1984. From 2000 to the present, Dr. Stern has also served as the vice president of Aqua-Eez, Inc., an affiliate of Multigon Industries, Inc. that manufactures and sells a hydrotherapy pool for labor and delivery. From 1972 to 1983, he was the president of Unigon Industries, Inc., which manufactured and distributed diagnostic ultrasound for vascular and neurological diagnostics. Dr. Stern received his Ph.D. in engineering and physics from Columbia University and holds an M.S. and a B.S. degree in electrical engineering from Columbia University and City College of New York, respectively. Dr. Stern's qualifications to serve on our board of directors include his significant scientific background and over 30 years of executive leadership experience in the field of medical devices and ultrasound technology.

Stephen Brown, Chief Financial Officer. Mr. Brown has served as our chief financial officer since February 3, 2015. Since 2009, Mr. Brown has been a managing partner of The Mcguffin Group Financial, a financial consulting firm concentrating on advising early stage companies including GMA Fund LLC, e-Prodigy Financial, LLC and The YGM Group, LLC. Mr. Brown has also served as a partner in an accounting and tax practice at Brown, Brown and Associates since 2009. From April 1995 to January 2009, Mr. Brown served in several executive positions, including chief financial officer, at IDT Corporation, a NYSE listed telecommunications company. During this time, Mr. Brown also served on IDT's board of directors for six years and on the Board of Net2Phone Inc. for five years. Mr. Brown was also the founder and chairman of IDT Entertainment Inc., a movie studio and media subsidiary. Mr. Brown is a certified public accountant and a member of the Academy of Television Arts and Sciences and serves on the board of directors of several educational institutions, including serving on the board of governors of Touro College.

Harold Jacob, M.D., Chief Medical Officer and Director. Dr. Jacob has served as our chief medical officer since March 1, 2015 and as our director since September 2003. From September 2003 to February 4, 2015, Dr. Jacob served as chairman of our board of directors and from September 2003 to March 1, 2015, Dr. Jacob served as our chief executive officer. Dr. Jacob also performed the functions of a principal financial officer until April 1, 2015. Dr. Jacob is our co-founder and has worked extensively in medical device development. Dr. Jacob also served part-time as an attending gastroenterologist at Shaare Zedek Medical Center in Jerusalem, Israel from 2004 to March 2011. Since April 2011, he has been an attending physician in Gastroenterology at Hadassah University Hospital in Jerusalem, Israel. From 1999 to the present, Dr. Jacob has served as the president of Medical Instrument Development Inc., which provides consulting services to start-up and early stage companies and patents its own proprietary medical devices. From 1997 to 2003, Dr. Jacob served as director of medical affairs at Given Imaging Ltd., a company that developed the first swallowable wireless pill camera for inspection of the intestines. Dr. Jacob also formerly served as a director for Oramed Pharmaceuticals Inc., a pharmaceutical company focused on the development of innovative orally ingestible capsule medication. We believe that Dr. Jacob's qualifications to serve on our board include his years of experience in the biomedical industry and with our Company and his experience serving in management roles of various companies.

Jona Zumeris, Ph.D., Vice President of Technology and Director. Dr. Zumeris is our co-founder and has served as our vice president of technology since September 2003. From 1999 to 2003, Professor Zumeris served as director of research and development for PMG Medica Ltd., a medical device company focused on ultrasound and piezomechanics technology. Dr. Zumeris was a founder, president and director of research and development of Nanomotion Ltd., a company that designs and manufactures motion solutions using ceramic servo motors, drivers and controllers, from 1993 to 1996. Dr. Zumeris's extensive experience in the nano-technology and medical fields, especially in leadership and research roles, provide him the appropriate experience to serve on our board.

Christopher Fashek, Chairman of the Board. Mr. Fashek is an accomplished healthcare executive with a record of leading global medical device and pharmaceutical businesses. Recognized as a visionary and pioneer in the advanced wound care sector, Mr. Fashek led the team that introduced V.A.C. therapy, a negative pressure wound therapy, to both the clinical community and patients with serious or complex wounds. He was the Vice Chairman, CEO and President of KCI USA, the Chairman of the Board at Systagenix Ltd, the Chairman of the Board and CEO of Spiracur Inc. and current CEO of Atteris Healthcare LLC, a startup in San Antonio, Texas. He has a BA from Upsala College and a MBA from Fairleigh Dickinson University.

Martin Goldstein, M.D., Director. Dr. Goldstein has served as our director since March 25, 2015. Dr. Goldstein has been a practicing urologist since 2000, with particular expertise in the management of stone disease. Dr. Goldstein is also an entrepreneur in the medical field. He is an executive director of New Jersey Urology, one of the largest urology group practices in the country, which he helped develop, and a co-founder and member of the executive board of Metropolitan Surgery Center, a large multispecialty ambulatory surgery center. Dr. Goldstein is co-founder and co-inventor of a medical device company that has received a Binational Industrial Research and Development (BIRD) Foundation grant. Dr. Goldstein brings to our board of directors his medical practice expertise. He is expected to make a valuable contribution in connection with marketing and facilitating the acceptance of our product offerings within the medical community. We also expect that he will provide assistance with the U.S. Food and Drug Administration regulatory approval process of our products, particularly our urology offerings. Additionally, we expect Dr. Goldstein to advise regarding the development of new products and innovations.

Michael Ferguson, Director. The Honorable Mr. Ferguson has served as our director since April 27, 2015. Mr. Ferguson is currently a senior advisor at BakerHostetler serving as the leader of their Federal Policy team. In January 2009, Mr. Ferguson founded Ferguson Strategies, LLC, a government affairs and strategic business consulting firm, where he serves as the chief executive officer and chairman. From 2001 to January 2009, he served in the U.S. House of Representatives, representing New Jersey's 7th congressional district. While in Congress, he was a member of the House Energy and Commerce Committee, which has wide jurisdiction over the healthcare, telecommunications and energy industries. He served as vice chairman of the panel's Health Subcommittee, where he became a key member on health care issues and helped to ensure passage of the Medicare Part D prescription drug benefit in 2003. In addition, he served as a member of the Telecommunications and Internet Subcommittee as well as the Oversight and Investigations Subcommittee. Mr. Ferguson was also a member of the House Financial Services Committee, where he cosponsored the Sarbanes-Oxley Act of 2002 and helped enact the initial terrorism risk insurance law. Mr. Ferguson is currently the chairman of the Board of Commissioners of the New Jersey Sports and Exhibition Authority and also serves as a senior fellow of the Center for Medicine in the Public Interest's Odyssey Initiative for Biomedical Innovation and Human Health. He has also served on various corporate advisory boards and committees, including for Pfizer, Inc., the National Italian American Foundation and the United States Golf Association. Mr. Ferguson received a bachelor's degree in government from the University of Notre Dame and a master's of public policy degree with a specialization in education policy from Georgetown University. Mr. Ferguson brings to the board of directors his extensive background in government affairs, health care policy, and business strategy gained from his experiences in Congress and business consulting, which we believe will assist in strengthening and advancing our strategic focus and regulatory compliance.

Thomas R. Mika, Director. Mr. Mika has served as our director since April 27, 2015. Mr. Mika has over 25 years of senior management, finance and consulting experience. Mr. Mika is currently Chief Financial Officer of POET Technologies, Inc. (TSX Venture: PTK) and previously served as chairman of the board of Rennova Health, Inc. (NASDAQ: RNVA) and as CEO of its wholly owned subsidiary, CollabRx, Inc. (NASDAQ: CLRX). Rennova Health is a vertically integrated public healthcare holding company that merged with CollabRx in November 2015 and became listed on the NASDAQ. CollabRx, formerly known as Tegal Corporation (NASDAQ: TGAL), is a clinical decision-support company that delivers expert solutions in precision oncology and genomic medicine. Mr. Mika was the Chairman & CEO of CollabRx and its predecessor company since March 2005. From 1992 to 2002, Mr. Mika served on the company's board of directors, which included periods of service as the chairman of the compensation committee and a member of the audit committee. Previously, Mr. Mika co-founded IMTEC, a boutique investment and consulting firm whose areas of focus included health care, pharmaceuticals, media and information technology. As a partner of IMTEC, Mr. Mika served clients in the U.S., Europe and Japan over a period of 20 years, taking on the role of chief executive officer in several ventures. Earlier in his career, Mika was a managing consultant with Cresap, McCormick & Paget and a policy analyst for the National Science Foundation. Mr. Mika holds a Bachelor of Science degree in Microbiology from the University of Illinois at Urbana-Champaign and a Master of Business Administration degree from the Harvard Graduate School of Business. Mr. Mika's qualifications to serve on our board of directors include his significant strategic and business insight from his prior service on the board of directors of other publicly held companies, as well as his substantial senior management, finance and consulting experience.

There are no family relationships among any of our directors and executive officers. Our executive officers are party to certain agreements related to their service as such, described in "Item 6. Executive Compensation."

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who own more than ten percent of our common stock, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Directors, officers and persons who own more than ten percent of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us, during the fiscal year ended December 31, 2016, each of our directors, officers and greater than ten percent shareholders complied with all Section 16(a) filing requirements applicable to our directors, officers and greater than ten percent shareholders.

Code of Ethics

In March 2017, we adopted a code of ethics that applies to our principal executive officer, principal financial officer, executives and key employees. A copy of the code of ethics is attached as Exhibit 14.1 to this report.

Board Committees

We do not currently have any committees of the board of directors. The board of directors serves as our audit committee.

ITEM 11. EXECUTIVE COMPENSATION

2016 and 2015 Summary Compensation Table

The table below sets forth, for our last two fiscal years, the compensation earned by our named executive officers, Brian Murphy, our chief executive officer, William Stern Ph.D., our President and former chief executive officer, Stephen Brown, our chief financial officer, Harold Jacob, M.D., our former chief executive officer and former chairman of the board of directors (now our chief medical officer and a member of our board of directors), and Jona Zumeris, our Vice President of Technology. No other executive officer had compensation of greater than $100,000 for the last three fiscal years.

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)	Option Awards ($)(2)	All Other Compensation ($)(1)	Total ($)(1)
Harold Jacob, M.D.	2016	-	-	-	10,763(3)	10,763
Former Chief Executive Officer and Former Chairman of the Board of Directors	2015	-	-		10,809(3)	10,809
Brian Murphy	2016	31,690(4)	-(4)	21,250	-	52,940
Chief Executive Officer	2015	-	-	-	-	-
William Stern, Ph.D.	2016	48,000(5)	10,600	117,311	-	175,911
President, former Chief Executive Officer and Vice-Chairman/ Director	2015	36,000(5)	14,000	66,711	-	116,711
Stephen Brown	2016	90,000	28,000	31,624	-	149,624
Chief Financial Officer	2015	50,000	-	22,237	-	72,237
Jona Zumeris, Ph.D.	2016	111,128	-	31,624	42,033(6)	184,785
Vice President of Technology and Director	2015	87,958	-	22,237	42,492(6)	152,687

(1) Compensation amounts received in non-U.S. currency have been converted into U.S. dollars using the average exchange rate for the applicable year. The average exchange rate for each of 2016 and 2015 was 3.8406 NIS per dollar and 3.8869 NIS per dollar, respectively.

(2) The amounts in this column reflect the dollar amounts to be recognized for financial statement reporting purposes with respect to the twelve month period ended December 31, 2016 in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the grant date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see "Management's Discussion and Analysis of Financial Condition and Results of Operation - Critical Accounting Policies - Stock-based compensation" and Note 2—"Significant Accounting Policies" and Note 10—"Stockholders' Deficiency" of the Notes to Consolidated Financial Statements as of December 31, 2016, included in this Annual Report on Form 10-K.

(3) Represents car-related benefits for Dr. Jacob.
(4) Does not include $7,541 of salary due Mr. Murphy in December that was paid in January and a $50,000 bonus due Mr. Murphy in 2016 of which $25,000 was paid in January 2017.
(5) Comprised of payments obligated under a services agreement with Multigon for use its facilities and services. Dr. Stern is the president of Multigon.
(6) Comprised of car-related benefits for Dr. Zumeris of $18,021 in 2016 and $16,997 in 2015 and other benefits, comprised of contributions towards a pension fund, disability insurance, severance pay, an advanced study fund and recreation pay, of $24,012 in 2016 and $25,495 in 2015.

Agreement with Brian Murphy

On October 13, 2016, we entered into an employment agreement with Mr. Murphy. The term of the agreement continues until terminated. Either party may terminate the agreement for any reason by providing 90 days prior written notice to the other party. In addition, we may terminate the agreement for cause after a 60 day cure period. Mr. Murphy is entitled to the payment of his full base salary and all other earned and accrued benefits and contributions during such notice or cure period. "Cause" means termination because of: (a) theft, embezzlement, fraud, or willful or material misrepresentation; (b) indictment or conviction of, or pleading nolo contendere or guilty to, a felony, or a crime involving moral turpitude; (c) refusal to perform, or intentional disregard of, in any material respect, duties and responsibilities; and (d) a material breach of the employment agreement or any other agreement with us.

Under this employment agreement, the Company shall pay Mr. Murphy an annual salary of $181,000 less applicable payroll deductions and tax withholdings (the "Base Salary") for all services rendered by the him under this Agreement. Notwithstanding the foregoing, the Base Salary shall automatically increase to: (i) $200,000, less applicable payroll deductions and tax withholdings, effective as of January 1 of the calendar year immediately following any calendar year during which we generate gross sales (as determined in accordance with generally accepted accounting principles consistently applied) exceeding $1,000,000; and (ii) $225,000, less applicable payroll deductions and tax withholdings, effective as of January 1 of the calendar year immediately following any calendar year during which we generate gross sales (as determined in accordance with generally accepted accounting principles consistently applied) exceeding $2,000,000. The Company shall pay the Base Salary in accordance with our normal payroll practices.

Commencing in 2017, Mr. Murphy shall be eligible to receive an annual bonus ("Performance Bonus") during each year of the term of the agreement. In 2017, the Mr. Murphy shall be eligible to receive a target bonus in an amount of up to $150,000, less applicable payroll deductions and tax withholdings, as follows: (i) an amount of up to $100,000, less applicable payroll deductions and tax withholdings, based on the extent to which Mr. Murphy has met performance criteria for the year, as determined in good faith by the board of directors, which shall be paid in 2018 within thirty (30) days of our issuance of audited financial statements on Form 10-K, and (ii) an amount of up to $50,000, less applicable payroll deductions and tax withholdings, in the amount and payable on the date as determined in the sole discretion of the Chairman of the Board. For 2018 and all subsequent years of the Executive's employment during the Term, the Executive shall be eligible to receive a target bonus in an amount of up to $100,000, less applicable payroll deductions and tax withholdings, based on the extent to which Mr. Murphy has met performance criteria for the year, as determined in good faith by the board of directors, which shall be paid in the calendar year after the calendar year to which the Performance Bonus relates within thirty (30) days of our issuance of our audited financial statements on Form 10-K.

In addition, we agreed that should we complete a financing or series of financings during the term of the agreement that cause our securities to become listed on a national securities exchange registered under Section 6 of the Exchange Act, as amended (such as the New York Stock Exchange, the NASDAQ Stock Market, or the NYSE MKT)(the "Uplisting"), we shall pay the Mr. Murphy a one-time bonus of $75,000, less applicable payroll deductions and tax withholdings, provided that such listing occurs within six (6) months from the Effective Date (as defined in the employment agreement). This bonus payable in connection with the Uplisting shall be paid within thirty (30) days of the Uplisting.

Mr. Murphy's employment agreement also contains certain noncompetition, non-solicitation, non-disparagement, confidentiality and assignment of work product requirements for Mr. Murphy.

On November 14, 2016, we granted Mr. Murphy an option to purchase 183,359 shares of common stock at an exercise price of $6.00 per share. The options vest one-quarter annually over a four year period commencing on the one-year anniversary of the date of grant and have a term of ten years.

In December 2016, the chairman of the board of directors formerly approved the $50,000 portion of the $150,000 target bonus.

Compensation of Stephen Brown

Mr. Brown's salary and bonus was determined by the chairman of the board with consultation from members of the board of directors. On March 25, 2015, we granted Mr. Brown an option to purchase 61,000 shares of common stock at an exercise price of $2.57 per share. The options vest in three equal installments on March 25, 2016, 2017 and 2018, and have a term of ten years.

Compensation of William Stern, Ph.D.

Dr. Stern has served as our chief executive officer from February 2015 to October 2016 and has served as our president since October 2016. Dr. Stern served without cash compensation or other benefits until March 25, 2015. On March 25, 2015, we entered into an employment agreement with Dr. Stern. The term of the agreement continues until terminated. Either party may terminate the agreement for any reason by providing 90 days prior written notice to the other party. In addition, we may terminate the agreement for cause after a 30 day cure period. Dr. Stern is entitled to the payment of his full base salary and all other earned and accrued benefits and contributions during such notice or cure period. “Cause” means termination because of: (a) theft, embezzlement, fraud, or willful or material misrepresentation; (b) indictment or conviction of, or pleading nolo contendere or guilty to, a felony, or a crime involving moral turpitude; (c) refusal to perform, or intentional disregard of, in any material respect, duties and responsibilities; and (d) a material breach of the employment agreement or any other agreement with us.

Under this employment agreement, Dr. Stern is entitled to a fee of $100 per unit of our PainShield product sold in the United States or Canada for which we have received payment in full during the term of the employment agreement, including direct sales to end users and sales to distributors or dealers, excluding units sold through our existing Texas distributor, less applicable payroll deductions and tax withholdings.

Dr. Stern’s employment agreement also contains certain noncompetition, non-solicitation, non-disparagement, confidentiality and assignment of work product requirements for Dr. Stern.

On March 25, 2015, we granted Dr. Stern an option to purchase 183,000 shares of common stock at an exercise price of $2.57 per share. The options vest one-third annually commencing on the one-year anniversary of the date of grant and have a term of ten years. The options were granted under the NanoVibronix, Inc. 2014 Long-Term Incentive Plan.

On October 14, 2016, upon being named vice-chairman of the board of directors, we granted Dr. Stern an option to purchase 35,000 shares of common stock at an exercise price of $5.50 per share. The options vest in full on the one-year anniversary of the date of grant and have a term of ten years.

Agreement with Jona Zumeris, Ph.D.

NanoVibronix Ltd., our wholly-owned Israeli subsidiary, is party to an employment agreement with Dr. Zumeris, pursuant to which Dr. Zumeris serves as its vice president of technology. Dr. Zumeris’s salary pursuant to the agreement is 19,500 NIS per month, which was increased to 20,000 NIS per month by oral agreement commencing in December 2012, to 30,000 NIS per month by oral agreement commencing April 1, 2015 and to 35,000 NIS per month by oral agreement commencing January 1, 2016 and he is entitled to a car, which we lease on his behalf, and contributions towards a pension fund, disability insurance, severance pay and an advanced study fund and recreation pay, which are customary or statutorily prescribed in Israel. Dr. Zumeris is also entitled to 15 vacation days. Dr. Zumeris’s employment agreement contains confidentiality restrictions and other terms and provisions that are customary in Israel.

On June 16, 2015, we entered into a first amendment to the employment agreement pursuant to which, among other things, we agreed that Dr. Zumeris may only be terminated without cause with the approval of our board of directors.

On March 25, 2015, we granted Dr. Zumeris an option to purchase 61,000 shares of common stock at an exercise price of $2.57 per share. The options vest one-third annually commencing on the one-year anniversary of the date of grant and have a term of ten years. The options were granted under the NanoVibronix, Inc. 2014 Long-Term Incentive Plan.

Outstanding Equity Awards at Fiscal Year End

The following table provides information on the holdings of stock options of the named executive officer at December 31, 2016. This table includes unexercised and unvested options awards. Each outstanding award is shown separately.

	Option Awards				
Name	Date of Grant	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Harold Jacob, M.D.	December 13, 2007	4,286	-	72.45	December 13, 2017
	December 9, 2010	10,714	-	1.19	December 9, 2020
	March 28, 2013	108,571	-	0.07	March 28, 2023
Brian Murphy	November 14, 2016	-	183,359	6.00	November 14, 2026
Jona Zumeris, Ph.D.	March 28, 2013	111,429	-	0.07	March 28, 2023
	March 25, 2015	20,333	40,667	2.57	March 25, 2025
William Stern	March 25, 2015	61,000	122,000	2.57	March 25, 2025
	October 14, 2016	-	35,000	5.50	October 14, 2026
Stephen Brown	March 25, 2015	20,333	40,667	2.57	March 28, 2025

2004 Global Share Option Plan

In November 2004, our board of directors adopted the 2004 Global Share Option Plan, pursuant to which 400,000 shares of our common stock are reserved for issuance as awards to employees, directors, consultants and other service providers. The purpose of the 2004 Global Share Option Plan is to provide an incentive to attract and retain directors, officers, consultants, advisors and employees, to encourage a sense of proprietorship and stimulate an active interest of such persons in our development and financial success. The 2004 Global Share Option Plan which was administered by our board of directors expired on February 28, 2014.

NanoVibronix, Inc. 2014 Long-Term Incentive Plan

On February 28, 2014, our stockholders approved the NanoVibronix, Inc. 2014 Long-Term Incentive Plan, which was adopted by our board of directors on February 19, 2014. The NanoVibronix, Inc. 2014 Long-Term Incentive Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem, and which may be paid in cash, shares of our common stock, or a combination of cash and shares of our common stock. We have reserved a total of 714,286 shares of our common stock for awards under the NanoVibronix, Inc. 2014 Long-Term Incentive Plan, 100% of which may be delivered pursuant to incentive stock options.

The purpose of the NanoVibronix, Inc. 2014 Long-Term Incentive Plan is to provide an incentive to attract and retain services of key employees, key contractors, and outside directors whose services are considered valuable, to encourage a sense of proprietorship and to stimulate active interest of such persons in our development and financial success. The NanoVibronix, Inc. 2014 Long-Term Incentive Plan is intended to serve as an "umbrella" plan for us and our subsidiaries worldwide. Therefore, if so required, appendices may be added to the NanoVibronix, Inc. 2014 Long-Term Incentive Plan in order to accommodate local regulations in foreign countries that do not correspond to the scope of the NanoVibronix, Inc. 2014 Long-Term Incentive Plan. Unless terminated earlier by the board of directors, the NanoVibronix, Inc. 2014 Long-Term Incentive Plan will expire on February 19, 2024. As of December 31, 2016, 115,404 options were available for future issuance under the NanoVibronix, Inc. 2014 Long-Term Incentive Plan.

Director Compensation

The following table shows information concerning our directors, other than directors who are our named executive officers, for the twelve months ended December 31, 2016:

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All other Compensation ($)	Total ($)
Christopher Fashek	21,774	-	16,023	-	-	-	37,797
Thomas Mika	-	-	46,577	-	-	-	46,577
Michael Ferguson	-	-	49,773	-	-	-	49,773
Martin Goldstein	-	-	75,452	-	-	-	75,452
Ira Greenstein (1)	-	-	67,600	-	-	-	67,600

(1) Mr. Greenstein resigned from our board of directors as of March 31, 2017.

On October 13, 2016 we entered into an agreement with Christopher Fashek to serve as the Chairman of our board of directors. Under this agreement Mr. Fashek will be paid $100,000 per year payable in semi-monthly installments. Mr. Fashek will also receive a one-time bonus of $25,000 if our stock becomes listed on a registered national securities exchange within six months of his appointment. Mr. Fashek also received options to purchase 91,679 shares of our common stock at an exercise price of $5.50 per share. The options vest one-quarter annually over a four year period commencing on the one-year anniversary of the date of grant and have a term of ten years.

Outside of compensation to our chairman, Christopher Fashek, we paid no compensation to our non-employee directors for the one year period ended December 31, 2016 and have paid no compensation during 2017 to date. On March 25, 2015, we approved the following compensation package for independent directors: (i) an annual grant of options to purchase 20,000 shares of common stock to all independent directors; (ii) an additional annual grant of options to purchase 5,000 shares of common stock for service as the chairperson of a board committee; and (iii) an additional annual grant of options to purchase 2,500 shares of common stock for service as a member, but not the chairperson, of a board committee. On March 2016 we approved the following compensation package for independent directors: (i) an annual grant of options to purchase 20,000 shares of common stock to the Chairman of the board of directors; (ii) an additional annual grant of options to purchase 15,000 shares of common stock for service as the vice-chairman of the board of directors.

On July 18, 2016, we granted options to purchase 20,000 shares of common stock at an exercise price of $5.35 per share to board of directors members Martin Goldstein, Michael Ferguson and Thomas Mika. The options vest on the one-year anniversary of the date of grant and have a term of ten years. We also granted Mr. Greenstein an option to purchase 40,000 shares of common stock at an exercise price of $5.35 per share. These options vest on the one-year anniversary of the date of grant and have a term of ten years.

On November 14, 2016, we granted options to purchase 35,000 shares of common stock at an exercise price of $5.50 per share to our president William Stern upon accepting the position of vice-chairman of the board of directors. The options vest on the one-year anniversary of the date of grant and have a term of ten years.

In connection with Mr. Greenstein's resignation from our board of directors, on March 30, 2017, we amended the option agreement, dated March 25, 2015, we entered into with Mr. Greenstein for the grant of an option to purchase 30,000 shares of common stock at an exercise price of $2.57 per share, all of which have vested, and the option agreement, dated July 18, 2016, we entered into with Mr. Greenstein for the grant of an option to purchase 40,000 shares of common stock at an exercise price of $5.35 per share, all of which were vesting on July 18, 2017, to (i) accelerate the vesting of the option granted to Mr. Greenstein in 2016 so that it will be fully vested as of March 30, 2017, and (ii) permit Mr. Greenstein to exercise the options granted in 2015 and 2016 at any time prior to the expiration of the option period as set forth in the applicable option agreement.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 31, 2017 by:

- each person known by us to beneficially own more than 5.0% of our common stock;
- each of our directors;
- each of the named executive officers; and
- all of our directors and executive officers as a group.

The percentages of common stock beneficially owned are reported on the basis of regulations of the Securities and Exchange Commission governing the determination of beneficial ownership of securities. Under the rules of the Securities and Exchange Commission, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. Except as indicated in the footnotes to this table, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o NanoVibronix, Inc., 9 Derech Hashalom Street, Nesher, Israel 36651.

As of March 31, 2017, we had 2,632,710 shares of common stock and 1,951,261 shares of series C preferred stock outstanding.

In addition to the shares of common stock reported below, as described in the footnotes below the table, six stockholders beneficially own 100% of our issuable and issued series C preferred stock.

Name of Beneficial Owner	Number of Shares Beneficially Owned (1)	Percentage Beneficially Owned(1)
5% Owners		
Rennova Health, Inc. (f.k.a. CollabRx, Inc.) (2)	205,095	7.8%
IDT Corporation(3)	273,950(4)	9.9%
Paul Packer(5)	273,967(6)	9.9%
Miriam Winder-Kelly(7)	262,485(8)	9.8%
Orin Hirschman(9)	240,320(10)	9.1%
Officers and Directors		
William Stern, Ph.D.	122,000(11)	4.4%
Stephen Brown	40,667(12)	1.5%
Harold Jacob, M.D.	225,773(13)	8.2%
Jona Zumeris, Ph.D.	220,975(14)	7.9%
Martin Goldstein, M.D.	61,000(15)	2.3%
Michael Ferguson	20,000(16)	*
Thomas R. Mika	20,000(17)	*
All directors and executive officers as a group (7 persons)	710,415	22.3%

* Represents ownership of less than 1%.

(1) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assume the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 31, 2017. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

(2) Rennova Health, Inc. (f.k.a. CollabRx, Inc.)'s address is 400 South Australian Avenue, 8th Floor, West Palm Beach, FL 33401.

(3) IDT Corporation's address is 520 Broad Street, Newark, New Jersey 07102.

(4) Comprised of (i) 155,838 shares of common stock, (ii) 34,236 shares of common stock that may be purchased upon the exercise of warrants, (iii) 71,501 shares of common stock that may be issued upon the conversion of an equal number of shares of series C preferred stock held by a subsidiary of IDT Corporation and (iv) 12,375 shares of common stock that may be issued upon the conversion of an equal number of shares of series C preferred stock held by IDT Corporation. Does not include 582,791 shares of series C preferred stock, which IDT Corporation also holds. These shares of series C preferred stock are excluded, even though the terms of the series C preferred stock allow for conversion into common stock and voting on an as if converted basis with the common stock, because these rights are prohibited if their exercise will result in the holder having beneficial ownership of more than 9.99% of our common stock. Does not include 533,334 shares of common stock that may be purchased by IDT Corporation upon the exercise of warrants. These shares of common stock are excluded because the warrants contain provisions that block exercise if such exercise will result in the holder having beneficial ownership of more than 9.99% of our common stock.

(5) Mr. Packer's address is 805 Third Avenue, 15th Floor, New York, NY 10022.

(6) Based on information contained in Schedule 13G filed on February 12, 2017. Comprised of (i) 79,786 shares of common stock held by Globis Capital Partners, L.P., (ii) 45,585 shares of common stock held by Globis Overseas Fund, Ltd., (iii) 22,792 shares of common stock held by Mr. Packer, (iv) 30,571 shares of common stock that may be purchased upon the exercise of stock options held by Mr. Packer and (v) 95,233 shares of common stock to be issued upon the conversion of restricted series C preferred stock held by Globis Capital Partners, L.P.

Does not include the following, which Mr. Packer also beneficially owns: (i) 643,482 shares of common stock issuable upon conversion of series C preferred stock held by Globis Capital Partners, L.P., (ii) 227,114 shares of common stock issuable upon conversion of series C preferred stock held by Globis Overseas Fund, Ltd., (iii) 51,274 shares of common stock issuable upon conversion of series C preferred held by Globis International Investments L.L.C., (iv) 57,143 shares of common stock issuable upon conversion of series C preferred stock held by AYTA Consulting, LLC and (v) 210,883 shares of common stock issuable upon conversion of series C preferred stock held by Mr. Packer. These shares of common stock issuable upon conversion of the series C preferred stock are excluded, even though the terms of the series C preferred stock allow for conversion into common stock and voting on an as if converted basis with the common stock, because these rights are prohibited if the exercise of such conversion or voting rights will result in the holder having beneficial ownership of more than 9.99% of the issuer's common stock..

Does not include the following: (i) 613,198 shares of common stock that may be purchased by Globis Capital Partners, L.P. upon the exercise of warrants, and 25,424 shares of common stock that can be purchased by conversion of a note payable (ii) 173,740 shares of common stock that may be purchased by Globis Overseas Fund, Ltd. upon the exercise of warrants and 9,322 shares of common stock that can be purchased by conversion of a note payable, (iii) 61,000 shares of common stock that may be purchased by AYTA Consulting, LLC upon the exercise of warrants and (iv) 83,672 shares of common stock that may be purchased by Mr. Packer upon the exercise of warrant and 7,627 shares of common stock that can be purchased by conversion of note payable. These shares of common stock are excluded because the warrants contain provisions that block exercise if such exercise will result in the holder having beneficial ownership of more than 9.99% of our common stock.

Mr. Packer is the managing member of Globis Capital Advisors, L.L.C., which is the general partner of Globis Capital Partners, L.P. Mr. Packer is the managing member of Globis Capital, L.L.C., which is the general partner of Globis Capital Management, L.P., which is the investment manager of Globis Overseas Fund, Ltd. Mr. Packer is also the managing member of Globis International Investments L.L.C. Mr. Packer is deemed to have beneficial ownership of the shares held by Globis Capital Partners, L.P., Globis Overseas Fund, Ltd. and Globis International Investments L.L.C. Mr. Packer also controls, and is deemed to have beneficial ownership of the shares held by, AYTA Consulting, LLC.

(7) Ms. Winder-Kelly's address is 900 Abel Wolman Municipal Bldg. 200N. Holliday St. Baltimore, MD 21202.

(8) Comprised of (i) 215,355 shares of common stock and (ii) 47,130 shares of common stock that may be purchased upon the exercise of warrants.

(9) Mr. Hirschman's address is 6006 Berkeley Avenue, Baltimore, Maryland 21209.

(10) Based on information contained in Schedule 13G filed on February 13, 2017. Comprised of (i) 5,911 shares of common stock held by Mr. Hirschman, (ii) 1,299 shares of common stock that may be purchased upon the exercise of warrants held by Mr. Hirschman, (iii) 70,803 shares of common stock held by AIGH Investment Partners LLC, of which Mr. Hirschman serves as president, and (iv) 162,307 shares of common stock held by AIGH Investment Partners L.P., of which Mr. Hirschman serves as general partner.

Does not include 133,334 shares of common stock that may be purchased by AIGH Investment Partners, L.P. upon the exercise of warrants. These shares of common stock are excluded because the warrants contain provisions that block exercise if such exercise will result in the holder having beneficial ownership of more than 4.99% of our common stock.

(11) Comprised of 122,000 shares of common stock that may be purchased by Dr. Stern upon exercise of stock options that are currently exercisable or exercisable within 60 days.

(12) Comprised of 40,667 shares of common stock that may be purchased by Mr. Brown upon exercise of stock options that are currently exercisable or exercisable within 60 days.

(13) Comprised of (i) 64,178 shares of common stock held by Medical Instrument Development Inc., an entity controlled by Dr. Jacob, (ii) 25,662 shares of common stock held by Dr. Jacob, (iii) 12,362 shares of common stock that may be purchased by Medical Instrument Development Inc. upon the exercise of warrants, and (iv) 123,571 shares of common stock that may be purchased by Dr. Jacob upon the exercise of stock options.

(14) Comprised of (i) 68,879 shares of common stock held by Piezo Top Ltd, an entity controlled by Dr. Zumeris, and (ii) options to purchase 152,096 shares of common stock held by Dr. Zumeris that are currently exercisable or exercisable within 60 days.

(15) Comprised of 61,000 shares of common stock that may be purchased by Dr. Goldstein upon exercise of stock options that are currently exercisable or exercisable within 60 days.

(16) Comprised of 20,000 shares of common stock that may be purchased by Mr. Ferguson upon exercise of stock options that are exercisable within 60 days.

(17) Comprised of 20,000 shares of common stock that may be purchased by Mr. Mika upon exercise of stock options that are exercisable within 60 days.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information as of December 31, 2016 with respect to our equity compensation plans under which our equity securities are authorized for issuance:

	(a)	(b)	(c)
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants, and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by security holders	962,396	$ 3.30	-
Equity compensation plans not approved by security holders	332,181(1)	4.83	-
Total	1,294,577	$ 3.69	-

(1) Represents 57,143 shares of common stock issuable upon conversion of series C preferred stock granted to AYTA Consulting, LLC, a consultant to us, in the form of a series C preferred stock award, 183,359 shares of common stock issuable upon exercise of options granted to Brian Murphy and 91,679 shares of common stock issuable upon exercise of options granted to Christopher Fashek.

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

Certain Relationships and Related Transactions

Generally, we do not to enter into related party transactions unless the members of the board of directors who do not have an interest in the potential transaction have reviewed the transaction and determined that (i) we would not be able to obtain better terms by engaging in a transaction with a non-related party and (ii) the transaction is in our best interest. This policy applies generally to any transaction in which we are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the previous two completed fiscal years, and in which any related person had or will have a direct or indirect material interest. This policy is not currently in writing.

On February 5, 2013, March 28, 2013, June 3, 2013, August 5, 2013, October 7, 2013, December 9, 2013, February 6, 2015, April 1, 2015, May 15, 2015, June 16, 2015, August 7, 2015, September 7, 2015, October 13, 2015, November 19, 2015 and December 11, 2015, we issued secured convertible promissory notes to two funds controlled by Mr. Packer. The notes were initially issued in the original aggregate principal amount of $100,000. On each date listed above, such principal amount was increased by $100,000. The fifteenth amended and restated secured convertible promissory notes issued on December 11, 2015 had an original aggregate principal amount of $1,500,000.In addition, as amended, the convertible promissory notes were convertible either at the holders' option or upon maturity into shares of our series C preferred stock. On April 27, 2015, the holders of the convertible promissory notes elected to convert the outstanding principal and interest thereunder into shares of our series C preferred stock. On that date, an aggregate principal balance of $1,500,000 and $106,027 in accrued interest were converted into 603,769 shares of series C preferred stock.

In connection with the issuance of the notes described above, on each of February 5, 2013, March 28, 2013, June 3, 2013, August 5, 2013, October 7, 2013, December 9, 2013, February 6, 2015, April 1, 2015, May 15, 2015, June 16, 2015, August 7, 2015, September 7, 2015, October 13, 2015, November 19, 2015 and December 11, 2015, we issued warrants to purchase up to an aggregate of 37,594 shares of common stock, with an exercise price of $2.66 per share, subject to adjustment, to the two funds controlled by Mr. Packer. We have amended and restated these warrants to include provisions that block exercise if such exercise will result in the holder having beneficial ownership of more than 9.99% of our common stock. This limitation may be waived upon not less than 61 days' prior written notice to us, and will expire the day before the applicable warrant expires.

On February 25, 2015, we entered into a consulting agreement with AYTA Consulting, LLC, an entity controlled by Mr. Packer, pursuant to which AYTA Consulting, LLC agreed to provide certain financial and strategic advisory and consulting services to us in exchange for a restricted stock award grant of 57,143 shares of our common stock, subject to the terms and conditions of a separate restricted stock award agreement, as the sole compensation for its performance of the consulting services. The agreement will terminate upon (a) our initial public offering, (b) our becoming subject to the reporting requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, (c) our merger, share exchange or consolidation (other than one in which our stockholders own a majority of the voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of our assets, (d) written termination of the agreement by AYTA Consulting, LLC with 30 days written notice, or (e) our liquidation, dissolution or winding up. The 57,143 shares of restricted stock were granted to AYTA Consulting, LLC on February 25, 2015 pursuant to a restricted stock award agreement and will fully vest upon the occurrence of any of the events listed in (a), (b) or (c) above. On January 30, 2015, we entered into an agreement providing for the exchange of the shares subject to the award agreement for an equal number of shares of series C preferred stock, subject to the same restrictions as the restricted common stock. The shares of restricted series C preferred stock are subject to forfeiture until vested and will be forfeited if such shares have not vested on the later of December 31, 2019 or the date of AYTA Consulting, LLC's termination of service with us. These shares vested upon effectiveness of our Form 10 on April 10, 2015.

In January and February, 2015, we entered into securities purchase agreements with certain investors providing for the issuance of shares of common stock, series C preferred stock and warrants to purchase shares of our common stock. Pursuant to these agreements, we issued 666,667 shares of series C preferred stock, warrants to purchase 266,667 shares of common stock at an exercise price of $3.00 per share and warrants to purchase 266,667 shares of common stock at an exercise price of $6.00 per share, for aggregate consideration of $2,000,000 to a subsidiary of IDT Corporation, a greater than five percent stockholder of ours, and 166,667 shares of series C preferred stock, warrants to purchase 66,667 shares of common stock at an exercise price of $3.00 per share and warrants to purchase 66,667 shares of common stock at an exercise price of $6.00 per share, for aggregate consideration of $500,000, to entities controlled by Mr. Packer.

On March 25, 2015, we entered into a services agreement with Multigon Industries, Inc. ("Multigon"). Dr. Stern serves as the president of Multigon. Pursuant to the services agreement, we are required to pay Multigon $4,000 per month in exchange for the provision of services to us that include the use of Multigon's office, the provision of telephone, fax and utilities at such office, processing for shipping of our products, customer service, maintenance of quality, service and repair records and payment processing.

On March 25, 2015, we issued warrants to purchase up to 61,000 shares of common stock to AYTA Consulting, LLC as consideration for the provision of guidance and assistance in connection with the filing of our Form 10 and our becoming a public reporting company. The warrants have an exercise price of $2.66 per share, subject to adjustment, and contain a provision that blocks exercise if such exercise will result in the holder having beneficial ownership of more than 9.99% of our common stock. This limitation may be waived upon not less than 61 days' prior written notice to us, and will expire the day before the applicable warrant expires.

On March 25, 2015, we entered into an agreement with Dr. Goldstein, a member of our board of directors, pursuant to which, as consideration for his efforts developing, pursuing approval of, and/or raising market awareness and acceptance of our UroShield product and CathBot product and any other future vibrating urology catheter-related product, Dr. Goldstein is entitled to a fee of $62.50 per unit of such products sold by us in the United States or Canada during the term of the agreement, less applicable deductions and tax withholdings. At our option, the per unit fees may be paid in the form of cash or shares of our common stock. If any portion is paid in cash, within 30 days of receipt, Dr. Goldstein must purchase an amount of common stock in the open market, subject to any limitations or restrictions that may apply under applicable laws, such that the purchase price of the common stock purchased plus the value of any common stock provided as payment of the per unit fees in the given quarter equals at least 50% of the per unit fees paid for that quarter (less applicable taxes). The term of the agreement continues until terminated. Either party may terminate the agreement for any reason by providing 90 days prior written notice to the other party.

Effective January 27, 2017, 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 and warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of $6.00 per share, issued in January and February 2015, to extend the expiration date of the warrants for two additional years. Pursuant to the Warrant Amendment, warrants to purchase 266,667 shares of common stock at $3.00 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share will expire on January 29, 2019, and the warrants to purchase 140,000 shares of common stock at $3.00 per share and warrants to purchase 140,000 shares of common stock at $6.00 per share will expire on February 10, 2019, and the warrants to purchase 13,333 shares of common stock at $3.00 per share and warrants to purchase 13,333 shares of common stock at $6.00 per share will expire on February 23, 2019. The exercise price and all other terms of the original warrants remain the same. Holders of the warrants who entered into the Warrant Amendment with us include (i) a subsidiary of IDT Corporation, a greater than five percent stockholder of ours, who holds warrants to purchase 266,667 shares of common stock at $3.00 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share, and (ii) entities controlled by Mr. Packer and Mr. Packer, who holds warrants to purchase 66,666 shares of common stock at $3.00 per share and warrants to purchase 66,666 shares of common stock at $6.00 per share.

On March 1, 2017, we completed a bridge financing, pursuant to which the Company received from Mr. Packer and entities controlled by Mr. Packer (the "Investors") $250,000 of loans and issued to the Investors convertible promissory notes (the "March 2017 Notes") in an aggregate principal amount of $250,000 and seven-year warrants (the "March 2017 Warrants") to purchase an aggregate of 100,000 shares of common stock at an initial exercise price of $5.90 per share, subject to adjustment, and are immediately exercisable. The March 2017 Warrants contain a provision that blocks exercise if such exercise will result in the holder having beneficial ownership of more than 9.99% of our common stock. This limitation may be waived upon not less than 61 days' prior written notice to us, and will expire the day before the applicable warrant expires. The March 2017 Notes bear interest at a rate of 6% per annum and mature on 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 "March Notes Qualified Financing"). To the extent not previously converted, on the maturity date, each Investor will receive, at the option of the Investor, either (a) cash equal to the original principal amount of the March 2017 Note and interest then accrued and unpaid thereon, or (b) shares of our common stock or series C convertible preferred stock. Upon consummation of a March Notes 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 March Notes 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 March Notes Qualified Financing. If there is a change of control and the March 2017 Notes have not been previously converted otherwise, the Investors may, at their option, (a) receive an amount in cash equal to the sum of the original principal amount of the March 2017 Notes and interest then accrued and unpaid thereon, or (b) convert the March 2017 Notes and all accrued and unpaid interest thereon into shares of common stock or series C convertible preferred stock of the Company immediately prior to the closing of such change of control transaction.

Director Independence

Our board of directors has determined that Christopher Fashek, Michael Ferguson, Thomas R. Mika and our former director Ira Greenstein, who resigned from our board of directors on March 31, 2017, satisfy the requirements for independence set out in Section 5605(a)(2) of the Nasdaq Stock Market Rules and that they have no material relationship with us (other than being a director and/or a stockholder). In making its independence determinations, the board of directors sought to identify and analyze all of the facts and circumstances relating to any relationship between a director, his immediate family or affiliates and our company and our affiliates and did not rely on categorical standards other than those contained in the Nasdaq rule referenced above.

We do not currently have any committees of the board of directors. The board of directors serve as the audit committee.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents aggregate fees for professional services rendered by Kost Forer Gabbay & Kasierer, A Member of Ernst & Young Global, for the fiscal years ended December 31, 2016 and 2015.

	Year Ended December 31, 2016	Year Ended December 31, 2015
Audit fees	$ 75,000	$ 75,000
Audit-related fees	$ -	$ -
Tax fees	$ -	$ -
All other fees	$ -	$ -
Total	$ 75,000	$ 75,000

Audit Fees

Audit fees for the years ended December 31, 2016 and 2015 consist of fees related to the audit of our annual financial statements and the review of our interim quarterly financial statements.

Pre-Approval of Independent Registered Public Accounting Firm Fees and Services Policy

The board of directors considered the audit fees, audit-related fees, tax fees and other fees paid to our accountants, as disclosed above, and determined that the payment of such fees was compatible with maintaining the independence of the accountants.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

(1) Financial Statement Schedules:

(2) Financial Statement Schedules:

None

(3) Exhibits:

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

NANOVIBRONIX INC. AND ITS SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2016

U.S. DOLLARS IN THOUSANDS

INDEX

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of NanoVibronix Inc.

We have audited the accompanying consolidated balance sheets of NanoVibronix Inc. and its subsidiary ("the Company") as of December 31, 2016 and 2015, and the related consolidated statements of comprehensive loss, changes in stockholders' deficiency and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2016 and 2015 and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company has recurring losses from operations and accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Tel-Aviv, Israel
March 31, 2017

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	December 31,	
	2016	**2015**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 106	$ 1,614
Trade receivables	6	5
Prepaid expenses and other accounts receivable (Note 3)	42	86
Inventories (Note 4)	67	71
Total current assets	221	1,776
NON-CURRENT ASSETS:		
Long-term prepaid expense	5	-
Severance pay fund	257	197
Property and equipment, net (Note 5)	11	10
Total non- current assets	273	207
Total assets	$ 494	$ 1,983

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

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2016	**2015**
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Trade payables	$ 82	$ 58
Other accounts payables (Note 6)	483	239
Total current liabilities	565	297
NON- CURRENT LIABILITIES:		
Warrants to purchase Common stock (Note 8)	2,079	1,696
Accrued severance pay	349	199
Total long-term liabilities	2,428	1,895
COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)		
STOCKHOLDERS' DEFICIENCY (Note 10):		
Stock capital -		
Common stock of $ 0.001 par value - Authorized: 20,000,000 shares at December 31, 2016 and 2015; Issued and outstanding: 2,632,710 and 2,611,328 shares at December 31, 2016 and 2015, respectively	2	2
Series C Preferred stock of $ 0.001 par value - Authorized: 5,000,000 shares at December 31, 2016 and 2015; Issued and outstanding: 1,951,261 at December 31, 2016 and 2015, respectively	2	2
Additional paid-in capital	20,073	19,521
Accumulated deficit	(22,576)	(19,734)
Total stockholders' deficiency	(2,499)	(209)
Total liabilities and stockholders' deficiency	$ 494	$ 1,983

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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,	
	2016	**2015**
Revenues	$ 229	$ 147
Cost of revenues	88	49
Gross profit	141	98
Operating expenses:		
Research and development	584	399
Selling and marketing	514	377
General and administrative	1,359	746
Total operating expenses	2,457	1,522
Operating loss	(2,316)	(1,424)
Financial expense, net (Note 12)	398	1,432
Loss before taxes on income	(2,714)	(2,856)
Taxes on income (Note 11)	117	28
Net loss	$ (2,831)	$ (2,884)
Total comprehensive loss	$ (2,831)	$ (2,884)
Common stock and Preferred C stock basic and diluted net loss per share (Note 14)	$ (0.62)	$ (0.82)
Weighted average number of shares of Common stock and Preferred C stock used in computing basic and diluted net loss per share (Note 14)	4,578,470	3,536,348

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY

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

	Preferred C stocks		Common stocks		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficiency)
	Number	Amount	Number	Amount			
Balance as of January 1, 2015	394,232	*)	163,580	*)	11,234	(16,850)	(5,616)
Issuance of Common stock, net of issuance costs	-	-	216,667	*)	511	-	511
Issuance of Preferred C stock, net of issuance costs	833,333	*)	-	-	1,964	-	1,964
Issuance of warrants to Common stock	-	-	-	-	446	-	446
Conversion of Promissory Notes into Preferred B-1 stock and Preferred C stock	683,651	1	-	-	1,358	-	1,359
Conversion of Promissory Notes into Preferred B-2 stock and Preferred C stock	1,508,001	2	-	-	2,099	-	2,101
Conversion of Preferred A-1, A-2, B-1 and B-2 stock into Common stock	(2,128,868)	(2)	2,131,081	2	-	-	-
Conversion of Convertible Promissory Notes into Preferred C stock	603,769	1	-	-	1,605	-	1,606
Issuance of warrants to consultant	-	-	-	-	84	-	84
Issuance of Preferred C stock to a consultant	57,143	*)	-	-	*)	-	*)
Issuance of Common stock to a consultant	-	-	100,000	*)	*)	-	-
Stock-based compensation related to options granted to consultants and employees	-	-	-	-	220	-	220
Total comprehensive loss	-	-	-	-	-	(2,884)	(2,884)
Balance as of December 31, 2015	1,951,261	$ 2	2,611,328	$ 2	$ 19,521	$ (19,734)	$ (209)
Issuance of Common stocks upon exercise of options	-	-	12,382	*)	33	-	33
Issuance of Common stocks to consultant	-	-	9,000	*)	-	-	-
Stock-based compensation related to options granted to employees	-	-	-	-	459	-	459
ASU 2016-09 adoption, Note 2t	-	-	-	-	11	(11)	-
Stock-based compensation related to restricted stocks granted to consultant	-	-	-	-	49	-	49
Total comprehensive loss	-	-	-	-	-	(2,831)	(2,831)
Balance as of December 31, 2016	1,951,261	2	2,632,710	2	20,073	(22,576)	(2,499)

*) Represents an amount lower than $ 1 thousands.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (2,831)	$ (2,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	7	9
Stock based compensation	508	220
Benefit component of Promissory Notes	-	384
Revaluation of warrants to purchase Common stock	383	962
Decrease (increase) in trade receivables	(1)	16
Decrease (increase) in prepaid expenses and other accounts receivable	44	(67)
Decrease (increase) in inventories	4	(36)
Increase (decrease) in trade payables	24	(43)
Increase (decrease) in other accounts payable	244	(105)
Increase (decrease) in accrued severance pay, net	90	(1)
Increase in long term prepaid expense	(5)	-
Accrued interest on Promissory Notes	-	65
Net cash used in operating activities	(1,533)	(1,480)
Cash flows from investment activities:		
Purchase of property and equipment	(8)	(1)
Net cash used in investment activities	(8)	(1)
Cash flows from financing activities:		
Proceeds from issuance of Common stock, Preferred stock and warrants, net of issuance costs	-	3,005
Proceeds from exercise of options	33	-
Net cash provided by financing activities	33	3,005
Increase (Decrease) in cash and cash equivalents	(1,508)	1,524
Cash and cash equivalents at the beginning of the period	1,614	90
Cash and cash equivalents at the end of the period	$ 106	$ 1,614
Supplemental information and disclosure of non-cash financing transactions:		
Stock-based compensation- ASU 2016-09 adoption	11	-
Conversion of Promissory Notes into Preferred B-1, B-2 stock and Preferred C stock	$ -	$ 5,066

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

NOTE 1:- GENERAL

a. NanoVibronix Inc. ("the Company"), a U.S. (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 (Israel 2003) Ltd., a company registered in Israel, which commenced operations in October 2003.

b. 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 $2,831 during the year ended December 31, 2016, has an accumulated deficit of $22,576 as of December 31, 2016 and has accumulated negative cash flow from operating activities amounted to $1,533 for the year ended December 31, 2016. 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. 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.

c. On February 9, 2015, the Company filed a Registration Statement on Form 10 under the Securities Exchange Act of 1934, as amended, to register its Common stock under Section 12(g) of that act. The Form 10 was effective on April 10, 2015.

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.

b. Financial statements in U.S. dollars:

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

The majority of the Company's expenses, financing activities and revenues are denominated and determined in U.S. dollars. The Company's management believes that the U.S. dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future. Thus, the functional and reporting currency of the Company is the U.S. dollar.

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The Company's transactions and balances denominated in U.S. dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to U.S. dollars in accordance with the Accounting Standards Codification (ASC) 830, "Foreign Currency Matters". All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statements of comprehensive loss as financial income or expenses, as appropriate.

c. 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.

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 market value. 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 market value. As of December 31, 2016 and 2015, inventory write-downs were recorded in the amounts of $ 0 and $ 8, respectively.

f. Non-current prepaid expenses:

Non-current prepaid expenses consist of non-current lease deposits as security for the Company's motor vehicles leases.

g. 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:

	%
Computers and peripheral equipment	33
Office furniture and equipment	7 – 15

h. 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, 2016 and 2015, 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, 2016 and 2015 amounted to $ 150 and $ 32, respectively.

j. Warrants:

The Company accounts for certain warrants held by investors which include down round protection as a liability according to 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 the 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. Revenue recognition:

The Company generates revenues from the sale of its products to distributors and patients. Revenues from those products are 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.

l. Research and development costs:

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

m. Income taxes:

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

The Company implements a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement. As of December 31, 2016 and 2015, the Company has recorded a liability for uncertain tax position in connection to the subsidiary's revenues related to stock based compensation expenses on a cost plus 5% basis.

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

n. 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 comprehensive loss.

The Company has early adopted Accounting Standard Update ("ASU") 2016-09, "Compensation - Stock Compensation", in the current consolidated financial statements and account for forfeitures as they occur. See also Note 2t.

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.

The fair value for options granted in 2016 and 2015 is estimated at the date of grant using a Black-Scholes-Merton options pricing model with the following underlying assumptions:

	Year ended December 31,	
	2016	**2015**
Risk free interest	1.21%-1.88%	1.44%-1.61%
Dividend yields	0%	0%
Volatility	61.3%-63.9%	65.3%-66.8%
Expected term (in years)	5.5-6.25	6

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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

o. 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.

p. Convertible promissory notes:

The Company applies ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20"), when it cannot elect the fair value option under ASC 825, "Financial Instruments." In accordance with ASC 470-20, the Company first allocates the proceeds to freestanding liability instrument that are measured at fair value at each reporting date, based on their fair value. The remaining proceeds are allocated between the convertible debt and all other freestanding instruments based on the relative fair values of the instruments at the time of issuance. In accordance with ASC 815 "Derivatives and Hedging" ("ASC 815"), the Company bifurcates all embedded derivatives that require bifurcation and accounts for them separately from the convertible debt.

In addition, under the guidelines of ASC 470-20, the Company measures and recognizes the embedded beneficial conversion feature on the commitment date. The beneficial conversion feature is measured by allocating a portion of the proceeds equal to the intrinsic value of the feature to additional paid-in-capital. The intrinsic value of the feature is calculated on the commitment date using the effective conversion price which had resulted subsequent to the allocation of the proceeds between the convertible debt and all other freestanding instruments. This intrinsic value is limited to the portion of the proceeds allocated to the convertible debt.

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

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 and Preferred C stock outstanding during each year. Diluted net loss per share is computed based on the weighted average number of shares of Common stock and Preferred C stock outstanding during each year plus dilutive potential equivalent shares of Common stock and Preferred C stock considered outstanding during the year, in accordance with ASC 260, "Earnings per Share." See also Note 14.

For the years ended December 31, 2016 and 2015, 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.

s. Contingent liabilities:

The Company accounts for its contingent liabilities in accordance with ASC 450 "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of December 31, 2016 and 2015, the Company is not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

t. Impact of recently issued accounting standards:

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). On July 9, 2015 the FASB voted to approve a one-year delay of the effective date and to permit companies to voluntarily adopt the new standard as of the original effective date. The new standard is effective for reporting periods beginning after December 15, 2018. The standard will supersede existing revenue recognition guidance, including industry-specific guidance, and will provide companies with a single revenue recognition model for recognizing revenue from contracts with customers.

The standard requires revenue to be recognized when promised goods or services are transferred to customers in amounts that reflect the consideration to which the company expects to be entitled in exchange for those goods or services. Adoption of the new rules could affect the timing of revenue recognition for certain transactions. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application.

In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing" ("ASU 2016-10"), which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. The amendment will be effective with ASU 2014-09.

In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients" ("ASU 2016-12"), which amends the guidance in the new revenue standard on collectability, noncash consideration, presentation of sales tax, and transition. The amendments are intended to address implementation issues and provide additional practical expedients to reduce the cost and complexity of applying the new revenue standard. The new standard will be effective with ASU 2014-09.

In December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which clarifies specific aspects of ASU 2014-09, including allowing entities not to make quantitative disclosures about remaining performance obligations in certain cases and requiring entities that use any of the new or previously existing optional exemptions to expand their qualitative disclosures. The new standard also makes twelve other technical corrections and improvements to ASU 2014-09. The new standard will be effective with ASU 2014-09.

The Company is still in the process of completing its assessment on the impact this guidance will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB ASU 2016-02-Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840. The standard is effective on January 1, 2020, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting". The update simplifies certain aspects of the accounting for share-based payment transactions, including income taxes, classification of awards and classification in the statement of cash flows and forfeiture rate calculation. The amendments of this ASU are effective for reporting periods beginning after December 15, 2016 for public entities. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted however all of the guidance must be adopted in the same period.

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The Company has early adopted ASU 2016-09 in the current 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, 2016.

NOTE 3:- PREPAID EXPENSES AND OTHER ACCOUNTS RECEIVABLE

	December 31,	
	2016	**2015**
Prepaid expenses	$ 34	$ 50
Other accounts receivable	8	36
	$ 42	$ 86

NOTE 4:- INVENTORIES

	December 31,	
	2016	**2015**
Raw materials	$ 44	$ 53
Work in process	5	4
Finished goods	18	14
	$ 67	$ 71

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

NOTE 5:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2016	2015
Cost:		
Computers and peripheral equipment	$ 48	$ 100
Office furniture and equipment	3	10
	51	110
Accumulated depreciation:		
Computers and peripheral equipment	38	91
Office furniture and equipment	2	9
	40	100
Depreciated cost	$ 11	$ 10

During the year ended December 31, 2016 total cost and accumulated depreciation of $ 67 related to fully depreciated fixed assets were disposed from the consolidated balance sheets.

Depreciation expenses for the years ended December 31, 2016 and 2015 were $7 and $9 respectively.

NOTE 6:- OTHER ACCOUNTS PAYABLE

	December 31,	
	2016	2015
Employees and payroll accruals	$ 170	$ 95
Accrued expenses	99	47
Income tax accrual	214	97
	483	239

NOTE 7:- CONVERTIBLE PROMISSORY NOTES

a. In November 2011, the Company issued Convertible B-1 Promissory Notes (the "B-1 Promissory Notes") to new and existing stockholders for a consideration of $ 1,000. The B-1 Promissory Notes bore 10% annual interest and were automatically convertible into Series B-1 Participating Convertible Preferred stock ("Series B-1 Preferred stock") upon certain events as defined in the agreement, at a fixed conversion price of $ 0.284 per share. If the B-1 Promissory Notes were not converted, the Company was required to pay the unpaid principal amount and interest accrued on the earlier of an "Event of Default" (as defined in the agreement) or November 15, 2015 (the "Maturity Date").

Following the above, the Company's then outstanding old Series B Participating Convertible Preferred stock ("Old Series B Preferred stock") and warrants to purchase Old Series B Preferred stock, issued during 2009 through 2011, were automatically cancelled and the holders of the Old Series B Preferred stock received Convertible B-2 Promissory Notes (the "B-2 Promissory Notes") in an aggregate amount of $ 1,557. The terms of the B-2 Promissory Notes terms were identical to those of the B-1 Promissory Notes, except that such B-2 Promissory Notes were convertible into shares of series B-2 Participating Convertible Preferred stock ("Series B-2 Preferred stock") and the conversion price set forth in such notes was $ 0.199 per share (reflecting a 30% discount on the B-1 Promissory Notes' conversion price mentioned above).

The B-1 Promissory Notes and the B-2 Promissory Notes are considered to be a liability pursuant to ASC 480 "Distinguishing Liabilities from Equity." The convertible notes are presented at accreted value, which includes the principal amount of the convertible notes less any discount and accumulated interest accrued over the term of the convertible notes, using the interest method.

In addition, the Company issued to the holders of the warrants to purchase Old Series B Preferred stock new warrants to purchase 2,319,062 shares of Series B-2 Preferred stock with a fixed exercise price of $ 0.199 (reflecting a 30% discount on the fair value of the Company's Preferred stock on that date). The warrants expire on November 15, 2018. The fair value of the warrants on the issuance date was $ 571 and was recorded as equity in accordance with ASC 470. 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.

As a result of issuing the warrants and as a result of the discount on the conversion price of the B-2 Promissory Note, the Company recorded in 2011 benefit component in the amount of $ 1,142, to be amortized over the terms of the B-2 Promissory Notes.

The Company's B-1 Promissory Notes and B-2 Promissory Notes were to mature on November 15, 2015. On April 28, 2015, the Company entered into a master amendment agreement with certain major stockholders, detailed below, pursuant to which the series B-1 promissory notes and series B-2 promissory notes held by them were amended to be convertible into shares of Series C Preferred stock.

b. During February 2013, the Company signed a convertible promissory notes agreement ("The Agreement") and issued convertible promissory notes ("The Notes") to certain investors. In addition, the Company issued to the stockholder warrants to purchase 37,594 shares of Common stock. The exercise price at which the warrants may be exercised is $ 2.66 per share, subject to adjustment for stock splits, fundamental transactions or similar events. The warrants expire within a period of five years, based on the issuance date.

As of December 31, 2013, the Company had signed a second, third, fourth and fifth amendment to The Agreement, amended and restated The Notes and issued warrants to purchase an additional 37,594 shares of Common stock per amendment in consideration for a principal amount of $ 600.

During February 2014 through December 2014, the Company signed a sixth, seventh, eighth, ninth, tenth, eleventh, twelfth, thirteenth and fourteenth amendment to The Agreement, amended and restated the Notes with each amendment and issued warrants to purchase an additional 37,594 shares of Common stock per amendment in consideration for $ 900.

On April 28, 2015, the Company signed an amendment to The Agreement, pursuant to which The Notes were amended to be convertible into shares of Series C Preferred stock rather than Common stock. On the same date, the Company entered into a master amendment agreement with certain major stockholders pursuant to which the series B-1 promissory notes and series B-2 promissory notes held by them were amended to be convertible into shares of Series C Preferred stock rather than Common stock. Also on April 28, 2015, the Company amended the warrants to purchase shares of series B-2 participating convertible Preferred stock held by the entities party to the master amendment agreement to include provisions that block exercise if such exercise will result in the holder having beneficial ownership of more than 9.99% of the Company's Common stock. This limitation may be waived upon not less than 61 days prior written notice to the Company, and will expire the day before the applicable warrant expires.

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

NOTE 7:- CONVERTIBLE PROMISSORY NOTES (Cont.)

c. In January and February 2015, the Company entered into securities purchase agreements with certain investors providing for the issuance of shares of Common stock, shares of Series C Preferred stock and warrants to purchase shares of Common stock. Pursuant to these agreements, the Company issued an aggregate of 833,333 shares of Series C Preferred stock, 216,667 shares of Common stock and warrants to purchase 420,000 shares of Common stock at an exercise price of $3.00 per share and warrants to purchase 420,000 shares of Common stock at an exercise price of $ 6.00 per share, for aggregate consideration of $ 3,005 net of issuance costs of $ 145, which were previously recorded as deferred issuance costs.

d. In February 2015, upon the receipt by the Company of investment amounts aggregating $ 3,150, as described above, the B-1 Promissory Notes converted by their terms into an aggregate of 560,594 shares of the Company's Series B-1 Preferred stock and 123,057 shares of Series C Preferred stock, and the Company's B-2 Promissory Notes converted by their terms into an aggregate of 1,174,042 shares of Series B-2 Preferred stock and 333,959 shares of Series C Preferred stock.

e. In April 2015, the holders of the Fourteenth Amended and Restated Secured Convertible Promissory Notes elected to convert the outstanding principal and interest thereunder into 603,769 shares of the Company's Series C Preferred stock.

f. In April 2015, upon the effectiveness of the Company's Form 10 filed with the Securities and Exchange Commission, the outstanding shares of Series A-1 Preferred stock, Series A-2 Preferred stock, Series B-1 Preferred stock and Series B-2 Preferred stock converted by their terms into 2,131,081 shares of Common stock.

NOTE 8:- FAIR VALUE MEASUREMENTS

During February 2013 through December 2014, the Company issued to the holders of The Notes warrants to purchase 563,910 shares of Common stock. The exercise price at which the warrants may be exercised is $ 2.66 per share, subject to adjustment for stock splits, fundamental transactions or similar events including "down round" protection. The warrants expire on February 2018 through December 2019, based on the issuance date (see also Note 7b).

The Company measures the 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 fair values being recognized in the Company's consolidated statement of comprehensive loss as financial income or expenses.

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

	December 31,	
	2016	**2015**
Dividend yield (1)	0%	0%
Expected volatility (2)	54.07%-65.59%	64.2%-66.9%
Risk-free interest (3)	0.89%-1.47%	1.19%-1.42%
Expected term (years) (4)	1.1-2.94	2.2-4.0

(1) Dividend yield - was based on the fact that the Company has not paid dividends to its stockholders in the past and does not expect to pay dividends to its stockholders in the future.

(2) Expected volatility - was calculated based on actual historical stock price movements of companies in the same industry over the term that is equivalent to the expected term of the option.

(3) Risk-free interest - based on yield rate of non-index linked U.S. Federal Reserve treasury stock.

(4) Expected term - the expected term was based on the maturity date of the warrants.

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

NOTE 8:- FAIR VALUE MEASUREMENTS (Cont.)

The level of inputs used to measure fair value was Level 2.

	Fair value of warrants to Common stock	
	2016	2015
Balance at January 1	$ 1,696	$ 734
Change in fair value of warrants	383	962
Balance at December 31	$ 2,079	$ 1,696

NOTE 9:- 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 2017.

Future minimum lease commitments under non-cancelable operating lease agreements as of December 31, 2016 are as follows:

Year ended December 31,	Operating leases
2017	$ 15
Total	$ 15

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 $30 and $31 for the years ended December 31, 2016 and 2015, respectively.

Motor vehicle leases, and related expenses were $17 and $13 for the years ended December 31, 2016 and 2015, respectively.

b. Royalties to the Office of the Chief Scientist ("the OCS"):

Under the Company's subsidiary research and development agreements with the OCS 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 OCS, up to an amount equal to 100% of the OCS research and development grants received, linked to the dollar including accrued interest at the LIBOR rate. 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, 2016 there are no sales from the funded projects.

As of December 31, 2016, the Company has a contingent obligation to pay royalties in the principal amount of approximately $ 480. In addition, the OCS may impose certain conditions on any arrangement under which it permits the Company to transfer technology or development out of Israel.

NOTE 10:- STOCKHOLDERS' DEFICIENCY

On May 7, 2014, the Company effected a reverse split of the Company's Common stock of seven (7) for one (1) (i.e., seven shares of Common stock, $ 0.001 nominal value each, will be combined into one share of Common stock $ 0.001 nominal value). All Common stock and per share data included in these financial statements for all periods presented have been retroactively adjusted to reflect the reverse split.

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.

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.

In January and February 2015, the Company entered into securities purchase agreements with certain investors providing for the issuance of shares of Common stock, shares of Series C Preferred stock and warrants to purchase shares of Common stock. Pursuant to these agreements, the Company issued an aggregate of 833,333 shares of Series C Preferred stock, 216,667 shares of Common stock and warrants to purchase 420,000 shares of Common stock at an exercise price of $3.00 per share and warrants to purchase 420,000 shares of Common stock at an exercise price of $ 6.00 per share, for aggregate consideration of $ 3,005 net of issuance costs of $ 145, which were previously recorded as deferred issuance costs.

In February 2015, upon the receipt by the Company of investment amounts aggregating $ 3,150, as described above, the B-1 Promissory Notes converted by their terms into an aggregate of 560,594 shares of the Company's Series B-1 Preferred stock and 123,057 shares of Series C Preferred stock, and the Company's B-2 Promissory Notes converted by their terms into an aggregate of 1,174,042 shares of Series B-2 Preferred stock and 333,959 shares of Series C Preferred stock.

In April 2015, the holders of the Fourteenth Amended and Restated Secured Convertible Promissory Notes elected to convert the outstanding principal and interest thereunder into 603,769 shares of the Company's Series C Preferred stock.

NOTE 10:- STOCKHOLDERS' DEFICIENCY (Cont.)

In April 2015, upon the effectiveness of the Company's Form 10 filed with the Securities and Exchange Commission, the outstanding shares of Series A-1 Preferred stock, Series A-2 Preferred stock, Series B-1 Preferred stock and Series B-2 Preferred stock converted by their terms into 2,131,081 shares of Common stock.

In April 2015, the Company issued 57,143 Series C Preferred stock to a related party 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.

c. In April 2015, the Company issued 100,000 shares of Common stock to its legal counsel as part of the total consideration for its legal services associated with the Company's fund raising.

d. In April 2016, 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, 2016. The stock based expense recognized in the financial statements for services received from the consultant in the year ended December 31, 2016 amounted to $49.

e. Warrants issued to investors:

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.

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 shall expire in February 2018 through December 2019, based on the issuance date (see also Note 8).

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 adjustment for stock splits, fundamental transactions or similar events. The warrants to purchase the 840,000 shares expire by February 2017. In January 2017 the Company agreed to extend the warrants to purchase the 840,000 shares by additional two years until February 2019 . See also Note 16.

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 have an exercise price of $2.57 per share, subject to adjustment for stock splits, fundamental transactions or similar events and shall expire on March 25, 2020.

f. 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.

In November 2014, 10 years after it was adopted, the Plan expired.

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.

As of December 31, 2016, under the New Plan, 115,404 options were available for future grants.

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

NOTE 10:- STOCKHOLDERS' DEFICIENCY (Cont.)

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

1. Option issued to employees and directors:

A summary of the Company's options activity and related information with respect to options granted to employees and directors during the years ended December 31, 2016 are as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life	Aggregate intrinsic value
Outstanding - beginning of the year	805,743	$ 2.80	8.40	2,564
Granted	410,038	$ 5.69		
Exercised	(12,382)	$ 2.66		
Expired or Forfeited	(1,393)	$ 38.36		
Outstanding - end of the year	1,202,006	$ 3.75	8.18	3,419
Vested and expected to vest	1,202,006	$ 3.75	8.18	3,419
Exercisable at end of year	510,968	$ 2.80	6.89	2,347

Weighted average fair value of options granted to employees and directors during the years 2016 and 2015 was $ 3.34 and $ 2 per option, respectively.

Aggregate intrinsic value of exercised options by employees and directors during the years 2016 and 2015 was $ 22, $ 0, respectively. The Aggregate intrinsic value of the exercised options represents the total intrinsic value (the difference between the sale price of the Company's share at the date of exercise, and the exercise price) 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 2016 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, 2016. This amount is impacted by the changes in the fair market value of the Company's shares.

As of December 31, 2016, the total unrecognized estimated compensation cost related to non-vested options granted prior to that date was $ 1,340 which is expected to be recognized over a weighted average period of approximately 2.02 years.

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

NOTE 10:- STOCKHOLDERS' DEFICIENCY (Cont.)

2. Option issued to non-employees:

The Company's outstanding options granted to consultants as of December 31, 2016 are as follows:

Issuance date	Options for Common stock	Weighted Average exercise price per share	Options exercisable	Expiration date
April 2007	357	$ 24.21	357	April 2017
December 2007	1,500	$ 84.56	1,500	December 2017
April 2009	1,071	$ 72.45	1,071	April 2019
December 2010	786	$ 1.99	786	December 2020
March 2013	30,000	$ 1.96	30,000	March 2023
October 2013	1,000	$ 1.96	1,000	October 2023
February 2015	714	$ 1.96	714	February 2025
Total	35,428	$ 7.81	35,428	

As of December 31, 2016, all options granted to non-employees are fully vested.

3. Stock-based compensation:

The stock based expense recognized in the financial statements for services received from employees is shown in the following table:

	Year ended December 31,	
	2016	2015
Research and development	$ 30	$ 22
Selling and marketing	12	9
General and administrative	417	189
Total	$ 459	$ 220

NOTE 11:- TAXES ON INCOME

a. As of December 31, 2016, the U.S. Company had federal and state net operating loss carry forward for tax purposes of approximately $ 11,125. The federal operating loss can be offset against taxable income for 20 years. Utilization of the U.S. net operating losses may be subject to substantial limitations due to the change of ownership provisions of the Internal Revenue Code of 1986.

b. Foreign tax:

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

2. The Israeli corporate tax rate in 2016 and 2015 is 25% and 26.5% respectively.

On January 5, 2016, the Israeli Parliament officially published the Law for the Amendment of the Israeli Tax Ordinance (Amendment 216), that reduces the corporate tax rate from 26.5% to 25%.

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

NOTE 11:- TAXES ON INCOME (Cont.)

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

3. The subsidiary has final tax assessments through 2010.

c. Loss before taxes on income:

	Year ended December 31,	
	2016	**2015**
Domestic	$ 1,884	$ 2,216
Foreign	830	640
	$ 2,714	$ 2,856

d. 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,	
	2016	**2015**
Deferred tax assets:		
Net operating loss carry forward	$ 3,894	$ 4,750
Temporary differences	34	10
Deferred tax assets before valuation allowance	3,928	4,760
Valuation allowance	(3,928)	(4,760)
Net deferred tax asset	$ -	$ -

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, 2016 and 2015.

e. 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.

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

NOTE 11:- TAXES ON INCOME (Cont.)

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

	December 31,	
	2016	2015
Balance at beginning of the year	$ 97	$ 58
Increase in unrecognized tax benefits as a result of tax positions taken	73	39
Balance at the end of the year	$ 170	$ 97

The Company recognizes interest and penalties related to unrecognized tax benefits in tax expense. During the year ended December 31, 2016 the Company accrued $16 for interest and penalties expenses related to uncertain tax positions.

NOTE 12:- FINANCIAL EXPENSE, NET

	Year ended December 31,	
	2016	2015
Interest on promissory notes	$ -	$ 65
Benefit component of promissory notes	-	384
Change in fair value of warrants	383	962
Other financial expense	15	21
	$ 398	$ 1,432

NOTE 13:- 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,	
	2016	2015
United States	$ 89	$ 52
Israel	13	14
Europe	52	28
India	24	7
Rest of the world	51	46
	$ 229	$ 147

During the year ended December 31, 2016, there were no sales to a single customer exceeding 10% of the Company's revenues.

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

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

NOTE 14:- BASIC AND DILUTED NET LOSS PER SHARE

Retrospective adjustment of net loss per share information

The Company has shares of Series C Preferred Stock outstanding which were issued in early 2015. The specific terms and conditions of the Series C Preferred Shares are disclosed in Note 10.

When preparing its consolidated financial statements for the year ended December 31, 2015, its interim consolidated financial statements for the respective quarters and year to date periods contained during 2015, and also the interim consolidated financial statements for the quarter ended March 31, 2016, the Company considered these convertible security to be a common stock equivalents but excluded them from its dilutive earnings (loss) per share computation as it concluded that the securities would be anti-dilutive in nature if or when converted. However, upon further analysis and when preparing it interim consolidated financial statements for the second quarter of 2016, the Company has concluded that these securities participate equally with common shares in the profits, losses and liquidation values of the Company, and while limited in voting they can be readily converted into voting common shares at any time. The Company has concluded that they are participating securities that should have been included as a component of both basic and dilutive earnings (loss) per share for all periods previously presented. Adjusted figures are presented below to reflect this revised conclusion.

	Year ended December 31, 2015
Net loss	2,884
Weighted average common shares as previously reported	1,978,395
Weighted average Series C Preferred shares outstanding	1,557,953
Basic and dilutive weighted average shares outstanding, as adjusted	**3,536,348**
Basic and dilutive loss per share, as adjusted	**(0.82)**

The Company has retrospectively adjusted for the foregoing matter in the accompanying consolidated financial statements for the year ended December 31, 2015.

The following table sets forth the computation of the Company's basic and diluted net loss per share of Common stock:

	Year ended December 31,	
	2016	2015
Net loss attributable to holders of Common stock as reported	$ (2,831)	$ (2,884)
Weighted average number of shares of Common stock and Preferred C stock used in computing basic and diluted net loss per share	$ 4,578,470	$ 3,536,348
Net loss per share of Common stock, basic and diluted	$ (0.62)	$ (0.82)

For the years ended December 31, 2016 and 2015, all outstanding options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

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

NOTE 15:- RELATED PARTIES BALANCES AND TRANSACTIONS

Balances with related parties:

	Year ended December 31,	
	2016	**2015**
Warrants to purchase Common stock (a)	$ 2,079	$ 1,696

Related parties' expenses:

	Year ended December 31,	
	2016	**2015**
Financial expenses (a)	$ 383	$ 962

(a) During February 2013 through December 2014, the Company issued to the holders of the Notes, who are related parties of the Company, warrants to purchase 563,910 shares of Common stock. The exercise price at which the warrants may be exercised is $ 2.66 per share, subject to adjustment for stock splits, fundamental transactions or similar events including "down round" protection. The warrants expire on February 2018 through December 2019, based on the issuance date (see also Note 7b).

NOTE 16:- SUBSEQUENT EVENTS

The Company evaluates events or transactions that occur after the balance sheet date but prior to the issuance of financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

On January 27, 2017, 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 and warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of $6.00 per share, issued in January and February 2015, to extend the expiration date of the warrants for two additional years. Pursuant to the Warrant Amendment, warrants to purchase 266,667 shares of common stock at $3.00 per share and warrants to purchase 266,667 shares of common stock at $6.00 per share were to expire on January 29, 2019, and the warrants to purchase 140,000 shares of common stock at $3.00 per share and warrants to purchase 140,000 shares of common stock at $6.00 per share were to expire on February 10, 2019, and the warrants to purchase 13,333 shares of common stock at $3.00 per share and warrants to purchase 13,333 shares of common stock at $6.00 per share were to expire on February 23, 2019. The exercise price and all other terms of the original warrants remain the same.

In March 2017, the Company completed a bridge financing, pursuant to which the Company received from four investors $350,000 of loans and issued to the investors convertible promissory notes (the “Notes”) in an aggregate principal amount of $350,000 and seven-year warrants (the “Warrants”) to purchase an aggregate of 140,000 shares of common stock (the “Warrant Shares”) at an exercise price of $5.90 per share (the “Exercise Price”).

NOTE 16:- SUBSEQUENT EVENTS (Cont.)

The principal amount and all accrued but unpaid interest on the Notes will become 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 (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, each investor will receive, at the option of the investor, either (a) cash equal to the original principal amount of the 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. If there is a change of control and the Notes have not been previously converted otherwise, the investors may, at their option, (a) receive an amount in cash equal to the sum of the original principal amount of the Notes and interest then accrued and unpaid thereon, or (b) convert the Notes and all accrued and unpaid interest thereon into shares of Common stock or Series C Convertible Preferred Stock of the Company immediately prior to the closing of such change of control transaction 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 implied by the exchange ratio set forth in the agreement governing such change of control transaction, 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, 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 the Company's capital stock.

The Warrants are immediately exercisable. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the resale of the Warrant Shares after the six month anniversary of the issuance date of the Warrants. The Exercise Price is adjustable for certain events, such as distribution of stock dividends, stock splits or fundamental transactions including mergers or sales of assets. A holder of the Warrants will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. 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 61 days after such notice to the Company.

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: July 26, 2017

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)	July 26, 2017
/s/ WILLIAM STERN William Stern	President and Director	July 26, 2017
/s/ STEPHEN BROWN Stephen Brown	Chief Financial Officer, (principal financial and accounting officer)	July 26, 2017
/s/ CHRISTOPHER FASHEK Christopher Fashek	Chairman of the Board of Directors	July 26, 2017
/s/ MARTIN GOLDSTEIN Martin Goldstein	Director	July 26, 2017
/s/ HAROLD JACOB M.D. Harold Jacob, M.D.	Director	July 26, 2017
/s/ JONA ZUMERIS, PH.D. Jona Zumeris, Ph.D.	Director	July 26, 2017
/s/ MICHAEL FERGUSON Michael Ferguson	Director	July 26, 2017
/s/ THOMAS R. MIKA Thomas R. Mika	Director	July 26, 2017

Index to Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 16, 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, 2015)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2015)
10.1	License Agreement, dated October 26, 2003, by and among NanoVibronix, Inc., Piezo-Top Ltd, and PMG Medica Ltd (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.2	License Agreement, dated December 11, 2011, by and between NanoVibronix, Inc. and AC Engineering Ltd. (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.3	Form of Series B-1 Promissory Note (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.4	Form of Subscription Agreement for Series B-1 Convertible Promissory Notes (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.5	Form of Series B-2 Promissory Note (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.6	Form of Series B-2 Participating Convertible Preferred Stock Purchase Warrant (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.7	Form of Subscription Agreement for Series B Convertible Preferred Stock and Warrants (incorporated by reference to Exhibit 10.7 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2015)
10.8	First Amendment to Subscription Agreement for Series B Convertible Preferred Stock and Warrants, dated November 14, 2011, by and between NanoVibronix, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.8 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2015)
10.9	Fourteenth Amended and Restated Securities Purchase Agreement, dated June 16, 2015, 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)
10.10	Fourteenth Amended and Restated Securities Purchase Agreement, dated December 11, 2015, 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)
10.11	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2015, 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)
10.12	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2015, 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)
10.13	Form of Amended and Restated 2013 and 2015 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, 2015)

10.14+	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, 2015)
10.15+	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, 2015)
10.16+	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, 2015)
10.17	Amendment to Subscription Agreement Convertible Promissory Notes, dated February 28, 2015, 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, 2015)
10.18	Amendment to Convertible Promissory Notes (Series B-1), dated February 28, 2015, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.18 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.19	Second Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2015, 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, 2015)
10.20	Third Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2015, 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, 2015)
10.21	Amendment to Convertible Promissory Notes (Series B-2), dated February 28, 2015, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.21 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.22	Master Amendment Agreement, dated March , 2015, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.22 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2015)
10.23+	Consulting Agreement, dated February 25, 2015, by and among NanoVibronix, Inc., NanoVibronix Ltd. and AYTA Consulting, LLC (incorporated by reference to Exhibit 10.23 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2015)
10.24+	Restricted Stock Award Agreement, dated February 25, 2015, by and between NanoVibronix, Inc. and AYTA Consulting, LLC (incorporated by reference to Exhibit 10.24 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2015)
10.25+	Employment Agreement, dated February 26, 2015, by and among NanoVibronix, Inc., NanoVibronix Ltd. and Ophir Shahaf (incorporated by reference to Exhibit 10.25 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.26+	Employment Agreement, dated March 2, 2015, by and among NanoVibronix, Inc., NanoVibronix Ltd. and Shay Ashkenazy (incorporated by reference to Exhibit 10.26 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2015)
10.27+	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, 2015)
10.28	Form of Amended and Restated Series B-2 Participating Convertible Preferred Stock Purchase Warrant (incorporated by reference to Exhibit 10.28 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2015)

10.29+	First Amendment to Personal Employment Agreement, dated June 16, 2015, 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, 2015)
10.30+	First Amendment to Employment Agreement, dated June 16, 2015, by and between NanoVibronix, Inc. and Ophir Shahaf (incorporated by reference to Exhibit 10.30 to Amendment No. 8 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 23, 2015)
10.31+	First Amendment to Employment Agreement, dated June 16, 2015, by and between NanoVibronix, Inc. and Shay Ashkenazy (incorporated by reference to Exhibit 10.31 to Amendment No. 8 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 23, 2015)
10.32	Second Amendment to Convertible Promissory Notes (Series B-1), dated January 28, 2015, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.32 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.33	Second Amendment to Convertible Promissory Notes (Series B-2), dated January 28, 2015, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.33 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.34+	Side Letter to Restricted Stock Award Agreement, dated January 30, 2015, by and between NanoVibronix, Inc. and AYTA Consulting, LLC (incorporated by reference to Exhibit 10.34 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015)
10.35	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).
10.36+	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).
10.37+	Side Letter to Consulting Agreement, dated March 25, 2015, by and among NanoVibronix, Inc. and AYTA Consulting, LLC (incorporated by reference to Exhibit 10.37 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015)
10.38+	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).
10.39+	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).
10.40+	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).
10.41+	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).
10.42+	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).
10.43+	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).
10.44+	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).
10.45+	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).
10.46	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 and Exchange Commission on March 31, 2017).
10.47	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).
10.48	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).
10.49	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).
10.50	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).
10.51+	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 and Exchange Commission on March 31, 2017).
10.52+	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 and Exchange Commission on March 31, 2017).
10.53+	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).
10.54+	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).
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2017).
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, 2015).
23.1*	Consent of Kost Forer Gabbay & Kasierer, a member firm of Ernst & Young Global

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, 2016, 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.

EXHIBIT 23.1

Consent of Independent registered public accounting firm

We consent to the incorporation by reference in the Registration Statements of Form S-8 (No. No. 333-205577) pertaining to the Stock Option Plan of NanoVibronix, Inc. of our report dated March 31, 2017 with respect to the consolidated financial statements of NanoVibronix, Inc. and its subsidiary, included in this Annual Report on Form 10-K/A for the year ended December 31, 2016.

/s/ Kost Forer Gabbay & Kaiserer
Kost Forer Gabbay and Kasierer
A Member of Ernst & Young Global

Tel-Aviv, Israel
July 26, 2017

EXHIBIT 31.1

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

I, Brian Murphy, certify that:

1. I have reviewed this Amendment No.1 to Annual Report on Form 10-K/A of NanoVibronix, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: July 26, 2017

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 Amendment No.1 to Annual Report on Form 10-K/A of NanoVibronix, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: July 26, 2017

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 Amendment No. 1 to Annual Report on Form 10-K/A (the "Form 10-K/A") for the year ended December 31, 2016 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/A 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/A 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: July 26, 2017

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/A 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/A 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 Amendment No. 1 to Annual Report on Form 10-K/A (the "Form 10-K/A") for the year ended December 31, 2016 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/A 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/A 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: July 26, 2017

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/A 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/A 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.

NANOVIBRONIX, INC.
9 DERECH HASHALOM STREET
NESHER, ISRAEL 36651
631-574-4410
Fax 631-574-4401
www.nanovibronix.com

July 26, 2017

VIA EDGAR

Division of Corporation Finance
Securities and Exchange Commission
Washington, D.C. 20549
Attention: Mr. Martin James
Mr. Dennis Hult

Re: NanoVibronix, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2016
Filed March 31, 2017
Form 10-Q for the Quarterly Period Ended March 31, 2017
Filed May 15, 2017
File No. 001-36445

Ladies and Gentlemen:

We are writing to respond to the comments set forth in the comment letter of the staff (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission"), dated July 13, 2017 ("Comment Letter"), relating to the above referenced Annual Report on Form 10-K, as originally filed on March 31, 2017, (the "Annual Report") and the Quarterly Report on Form 10-Q, as originally filed on May 15, 2017, (the "Quarterly Report"). In connection with this response to Comment Letter, we are contemporaneously filing via EDGAR an amendment to each of the Annual Report and Quarterly Report responding to the Staff's comments in the Comment Letter and updating the Annual Report and Quarterly Report, respectively.

The following are our responses to the Comment Letter. Our responses are numbered to correspond to the Staff's comments as numbered in the Comment Letter. For your convenience, each of the Staff's comments contained in the Comment Letter have been restated below in their entirety, with our corresponding response set forth immediately under such comment.

Form 10-K for the Year Ended December 31, 2016

Consolidated Financial Statements

Consolidated Statements of Comprehensive Loss, page F-5

1. **Revise this statement and other applicable sections of future filings to use parentheses to clearly show Operating loss, Loss before taxes on income, Net loss, and Total comprehensive loss as negative amounts, similar to your presentations of the net loss per share amounts here and net loss in the statements of cash flows.**

   Response:

   We have made the requested revisions to the Consolidated Statements of Comprehensive Loss on page F-5 to the amended Annual Report and page 5 to the amended Quarterly Report to use parentheses to clearly show Operating loss, Loss before taxes on income, Net loss, and Total comprehensive loss as negative amounts. Amendments to the Annual Report and Quarterly Report are transmitted herewith for filing. We note the Staff's comment and will include such changes in future filings.

Exhibits 31.1 and 31.2 Certifications Pursuant to Rule 13-a-14(a)

2. **On page 48, you correctly include Management's Report on Internal Control over Financial Reporting as of December 31, 2016. Please amend the filing to provide currently dated certifications that are consistent with the language in Item 601(b)(31) of Regulation S-K, including the required language pertaining to your the internal control over financial reporting in the introduction to paragraph 4 and paragraph 4(b) in its entirety. This comment also applies to your Form 10-Q for the period ended March 31, 2017.**

   Response:

   We have made the requested revisions to Exhibits 31.1 and 31.2 to the Annual Report and the Quarterly Report to provide currently dated certifications that are consistent with the language in Item 601(b)(31) of Regulation S-K, including the required language pertaining to our internal control over financial reporting in the introduction to paragraph 4 and paragraph 4(b) in its entirety. Amendments to the Annual Report and Quarterly Report are transmitted herewith for filing.

Very truly yours,

/s/ Stephen Brown

Stephen Brown, Chief Financial Officer