

EXPLANATORY NOTE

On November 3, 2017, the registrant previously filed this prospectus (the “Original Filing”) with the Securities and Exchange Commission. The registrant hereby refiles this prospectus for the sole purpose of correcting certain numerical values which were inadvertently misstated in the Prospectus Summary, Risk Factors, Capitalization, Dilution and Security Ownership of Certain Beneficial Owners and Management sections of the Original Filing. No other changes have been made to the Original Filing.

PROSPECTUS

**Filed pursuant to Rule 424(b)(4)
Registration No. 333-218871**



NanoVibronix, Inc.

**1,224,488 Shares of
Common Stock,
Warrants to Purchase up to 918,366 Shares of Common Stock
(918,366 Shares of Common Stock Underlying the Warrants)
and
1,225 Shares of Series D Convertible Preferred Stock
(1,224,488 Shares of Common Stock Underlying the Series D Convertible Preferred Stock)**

We are offering 1,224,488 shares of our common stock, together with warrants to purchase up to 918,366 shares of common stock (and the shares of common stock issuable from time to time upon exercise of the warrants), at an offering price of \$4.90 per share of common stock and accompanying warrant to purchase 0.75 of one share of common stock. The shares and warrants will be separately issued but will be purchased together in this offering. Each warrant will have an exercise price of \$6.95 per full share of common stock, will be exercisable upon issuance and will expire five years from the date on which such warrants were issued.

We are also offering to those purchasers, if any, whose purchase of our common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing common stock, to purchase Series D Convertible Preferred Stock (the “Preferred Stock”). Each share of Preferred Stock is being sold together with 1,000 of the same warrants to purchase 0.75 of one share of common stock described above being sold with each share of common stock. For each share of Preferred Stock purchased in this offering in lieu of common stock, we will reduce the number of shares of common stock being sold in the offering by 1,000. Pursuant to this prospectus, we are also offering the shares of common stock issuable upon conversion of the Preferred Stock.

Each share of Preferred Stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder will be prohibited from converting 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 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase 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 us. The shares of Preferred Stock will otherwise have the preferences, rights and limitations described under “Description of Securities - Series D Convertible Preferred Stock Being Issued in this Offering” beginning on page 90 of this prospectus.

Our common stock is currently quoted on the OTCQB over-the-counter marketplace under the symbol “NAOV.” As of October 31, 2017, the last reported sale price of our common stock as reported on the OTCQB over-the-counter marketplace was \$6.95 per share. The common stock offered hereby has been approved for listing on The NASDAQ Capital Market under the symbol “NAOV.” We do not intend to apply for any listing of the Preferred Stock or the warrants on The NASDAQ Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect that the Preferred Stock or the warrants will be quoted on the OTCQB over-the-counter marketplace. There is no established public trading market for the Preferred Stock or the warrants, and we do not expect a market to develop.

Investing in our securities (and the common stock underlying such securities) involves a high degree of risk. See “Risk Factors” beginning on page 9 of this prospectus before making a decision to purchase our securities.

We are an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012, or JOBS Act and, as such, have elected to comply with certain reduced public company reporting requirements.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share of Common Stock and Warrant	Per Share of Preferred Stock and Warrant	Total
Public offering price	\$ 4.90	\$ 4,900	\$ 5,999,991.20
Underwriting discounts and commissions (1)	\$.392	\$ 392	\$ 479,999.30
Proceeds, before expenses, to us	\$ 4.508	\$ 4,508	\$ 5,519,991.90

(1) The underwriters will receive compensation in addition to the underwriting discounts and commissions. See “Underwriting” beginning on page 96 of this prospectus for a description of the compensation payable to the underwriters.

We have granted the underwriters an option, exercisable one or more times in whole or in part, to purchase up to 183,673 additional shares of common stock (or up to 184 additional shares of Preferred Stock) and/or warrants to purchase up to an aggregate of 137,755 shares of common stock at an exercise price of \$ 6.95 per share, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of this prospectus to cover over-allotments, if any.

Certain of our affiliates have indicated an interest in participating in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these affiliates may determine to purchase fewer securities than they have indicated an interest in purchasing or not to purchase any securities in this offering.

The underwriters expect to deliver the shares of common stock and Preferred Stock and the Warrants against payment in New York, New York on or about November 6, 2017.

Dawson James Securities, Inc.

The date of this prospectus is November 1, 2017

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	9
Cautionary Note Regarding Forward Looking Statements	26
Use of Proceeds	27
Price Range of Our Common Stock	28
Dividend Policy	28
Capitalization	28
Dilution	30
Management’s Discussion and Analysis of Financial Condition and Results of Operation	31
Business	42
Management	67
Executive Compensation	72
Certain Relationships and Related Transactions	78
Security Ownership of Certain Beneficial Owners and Management	80
Material U.S. Federal Tax Consequences	83
Description of Securities	88
Underwriting	96
Legal Matters	99
Experts	99
Where You Can Find Additional Information	99
Index to Financial Statements	F-1

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry’s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates. See “Cautionary Note Regarding Forward-Looking Statements.”

This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary may not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and our historical financial statements and related notes included elsewhere in this prospectus before making an investment decision. In this prospectus, unless the context requires otherwise, all references to “we,” “our” and “us” refer to NanoVibronix, Inc., a publicly traded Delaware corporation and its consolidated subsidiaries.

Overview

We are a medical device company focusing on noninvasive biological response-activating devices that target biofilm prevention, wound healing and pain therapy and can be administered at home, without the assistance of medical professionals. In 2016, we were selected by the Israeli government as one of the companies to present at its “Israeli Innovation and Technologies in Africa and Developing Countries” conference. Our products, which are in various stages of clinical and market development, currently consist of:

- UroShield™, an ultrasound-based product that is designed to prevent bacterial colonization and biofilm in urinary catheters, increase antibiotic efficacy and decrease pain and discomfort associated with urinary catheter use.
- PainShield™, a patch-based therapeutic ultrasound technology to treat pain, muscle spasm and joint contractures by delivering a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area; and
- WoundShield™, a patch-based therapeutic ultrasound device intended to facilitate tissue regeneration and wound healing by using ultrasound to increase local capillary perfusion and tissue oxygenation.

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

PainShield is currently cleared for marketing in the United States by the U.S. Food and Drug Administration although there has not been a significant sales and marketing effort to date. 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 have consummated sales of PainShield and UroShield in the relevant markets, although to date sales have been minimal; WoundShield has not generated significant revenue to date. Outside of the United States, we generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

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

In addition to the need to obtain regulatory approvals, we anticipate that sales volumes and prices of our UroShield, WoundShield and PainShield products will depend in large part on the availability of insurance coverage and reimbursement for at-home use from third party payers. Third party payers include governmental programs such as Medicare and Medicaid in the United States, private insurance plans and workers' compensation plans. We do not currently have reimbursement codes for use of WoundShield in any of the markets in which we have regulatory authority to sell WoundShield. Of the markets in which we have regulatory authority to sell PainShield, we have reimbursement codes in the United States (i.e., Current Procedural Terminology codes or "CPT codes") for clinical use only, but do not have such reimbursement codes for at-home use of the product, although the product is marketed and sold for such use. With respect to UroShield, which may be used in a clinical and home setting, we do not currently have reimbursement codes in any of the markets in which we have regulatory authority to sell UroShield. We anticipate that we will begin to seek reimbursement codes for use of our products in the markets in which we have regulatory authority to sell such products, however, additional clinical data will be required in order to obtain such reimbursement codes. Our current ongoing research and planned research may facilitate our ability to obtain reimbursement codes and there is no guarantee that we will be successful in obtaining such codes quickly, or at all.

We have completed 5 separate clinical studies with UroShield that together evaluated approximately 139 patients with urinary catheters. In patients where the UroShield product was used there were no serious adverse events reported, while a variety of clinical beneficial observations were seen including: catheter biofilm reduction, reduction in catheter associated pain, reduction in urinary tract infections, and a significant decrease in bacteriuria rates. We are currently conducting a double blind clinical trial for UroShield in the United States in order to obtain 510(k) clearance from the U.S. Food and Drug Administration. In July 2017, we engaged Idonea Solutions, Inc., an FDA consultant, to assist in our efforts. If we are able to successfully obtain 510(k) clearance, we intend to pursue obtaining reimbursement codes and to target completion of partnerships with leading catheter product companies for sales and marketing efforts in the United States.

In addition, we are currently ramping up our clinical development and marketing efforts in North America with respect to PainShield. We are currently conducting a clinical trial to evaluate the effect of PainShield in patients with trigeminal neuralgia. We believe that a positive outcome in this trial will assist in our expanding the commercial use of this product through a direct sales effort that we intend to manage. We have also identified a market for PainShield in the professional sports industry, where in some cases reimbursement may be available from sports alumni organizations or, more likely, self-pay. In order to pursue this market, we are exhibiting at sports trainers meetings, pursuing alumni associations, advertising in their media, and negotiating with a sports trainer focused sales organization. The PainShield device is offered for sale to practitioners with a provider rental program which was implemented in January 2017. The PainShield product was also modified and enhanced through various accessories for use within the equine community. This market is currently being pursued through prominent equine clinicians and independent sales representatives and distributors. 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. We are pursuing appropriate distributors in the U.S. market with resources and qualifications to sell PainShield in the different segments of the pain treatment market.

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

Business Model

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

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

Ultrasound Technology and Our Products

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

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

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

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. In addition, micro vibrations induce skin surface nerve axon reflex and type IIa muscle fibers contraction rates, resulting in vasodilation.

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

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

Markets for Our Products

We believe our products compete and/or will compete in the markets described below:

- **Catheter Market.** Our UroShield product is complementary to products in the catheter market. The global catheter market totaled approximately \$26.6 billion in 2015 and it is expected to grow at a compound annual growth rate (“CAGR”) of 9.7% through 2021 (as reported by Zion Market Research). Approximately 25% of patients who are admitted to a hospital will have an indwelling catheter at some point during their stay and 7% of nursing home residents are managed by long term catheterization. In the United States there are 25 million Foley catheters sold annually and there are 75 million catheters sold elsewhere, yielding a total global Foley catheter market of 100 million units worldwide.
- **Pain Market.** Our PainShield product is aimed at the pain treatment market. Pain-related complaints are one of the most common reasons patients seek treatment from physicians. According to Landro L, “New Ways to Treat Pain: Tricking the Brain, Blocking the Nerves in Patients When all Else Has Failed,” Wall Street Journal, May 11, 2010, approximately 26% of adult Americans, or approximately 76.5 million people, suffer from chronic pain. The National Center for Health Statistics has estimated that 54% of the adult population experiences musculoskeletal pain.
- **Wound-Healing Devices Market.** Our WoundShield product is aimed at the market for wound-healing devices. The global wound care device market totaled approximately \$24 billion in 2015 and it is expected to grow at a CAGR of 6.7% during 2016-2022 (as reported by P&S Global Research in January 2017).

Risks Associated with Our Business

Our ability to operate our business and achieve our goals and strategies is subject to numerous risks as discussed more fully in the section titled “Risk Factors,” including, without limitation:

- 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 UroShield™;
- regulatory actions that could adversely affect the price of or demand for our approved products;
- favorable or unfavorable decisions about our products from government regulators, insurance companies or other third-party payers;
- protection of our intellectual property portfolio;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- unforeseen changes in healthcare reimbursement for any of our approved products, the loss of such reimbursement or the inability to obtain such reimbursement for use of our products at home, as well as in a clinical setting;
- insufficient or inadequate reimbursement by governmental and other third party payers for our 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;
- our failure to comply with regulatory guidelines;
- uncertainty in industry demand and patient wellness behavior;
- loss or retirement of key executives and qualified personnel;
- 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; and
- depth of the trading market in our common stock.

Conversion of Convertible Promissory Notes Upon Completion of this Offering

Since March 1, 2017, we have completed a series of bridge financings pursuant to which we have received aggregate proceeds of \$1,380,000 in exchange for convertible promissory notes in the aggregate principal amount of \$1,380,000, and seven-year warrants to purchase an aggregate of 552,000 shares of common stock at an exercise price of \$5.90 per share.

The notes issued in the bridge financings discussed above are collectively referred to in this prospectus as the “2017 Notes,” and the seven-year warrants issued in such bridge financings are collectively referred to in this prospectus as the “2017 Warrants.”

The principal amount and all accrued but unpaid interest on each 2017 Note will become due and payable on the earlier of the (i) 5-year anniversary of the date of issuance, or (ii) the date we complete an equity financing pursuant to which we issue and sell shares of capital stock resulting in aggregate proceeds of at least \$2,000,000 (a “Qualified Financing”). The 2017 Notes bear interest at a rate of 6% per annum. As of the expected closing date of this offering, the aggregate outstanding principal amount of the 2017 Notes and accrued but unpaid interest thereon was \$1,416,931.

Notwithstanding anything in the 2017 Notes to the contrary, all of the holders of the 2017 Notes have agreed to convert the outstanding principal and accrued but unpaid interest on their 2017 Notes into shares of our capital stock and enter into 180 day lock-up agreements with respect to such securities issued upon conversion of the 2017 Notes in the event we consummate a Qualified Financing prior to December 31, 2017, pursuant to a firm commitment underwritten offering that results in our common stock being contemporaneously listed on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market or the Nasdaq Global Select Market, upon the closing date of such Qualified Offering.

This offering will constitute a Qualified Financing, and therefore, upon closing of this offering, based on the outstanding principal amount and all accrued but unpaid interest on the 2017 Notes as of the expected closing date of this offering, at 80% of the offering price of \$4.90 per share of common stock and accompanying warrant, we will be required to issue an aggregate of 361,462 shares of common stock and warrants to purchase an aggregate of 271,096 shares of common stock (or Preferred Stock and warrants, if applicable) to the holders of the 2017 Notes, all of which will be subject to lock-up agreements for 180 days. Dawson James Securities, Inc. may, in its sole discretion, upon prior written consent, release all or any portion of the shares subject to the lock-up agreements.

In the absence of a Qualified Financing, on the maturity date, the holders of our 2017 Notes may elect to have the outstanding principal and accrued but unpaid interest thereon repaid in cash or converted into common stock. To the extent that the conversion of our 2017 Notes causes any holder thereof to beneficially own more than 9.99% of our common stock, such holder may elect to receive shares of our Series C Convertible Preferred Stock (the “Series C Preferred Stock”) in lieu of common stock or common stock equivalents. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Recent Events.”

Corporate Information

We were organized as a Delaware corporation on October 20, 2003. Our principal executive offices are located at 9 Derech Hashalom Street, Neshar, Israel 36651. Our telephone number is (914) 233-3004. Our website address is www.nanovibronix.com. Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

THE OFFERING

Issuer	NanoVibronix, Inc.
Common stock offered by us in this offering	1,224,488 shares of our common stock, par value \$0.001 per share.
Preferred Stock offered by us	We are also offering to those purchasers, if any, whose purchase of common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing common stock, to purchase up to 1,225 shares of Preferred Stock. This prospectus also relates to the offering of shares of common stock issuable upon conversion of the Preferred Stock.
Warrants	Each share of our common stock offered is being sold together with a warrant to purchase 0.75 of one share of common stock (each share of Preferred Stock issued in lieu of common stock will be sold together with 1,000 warrants to purchase 0.75 of one share of common stock). Each warrant will be exercisable at an initial exercise price of \$6.95 per full share of common stock. The warrants are exercisable at any time for a period of five years from the date on which such warrants are issued. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Conversion	Each share of Preferred Stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder will be prohibited from converting 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 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase 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 us.

Liquidation rights	In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to any beneficial ownership limitation), subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.
Voting Rights	The holders of the Preferred Stock have no voting rights, except as required by law. Any amendment to our certificate of incorporation, bylaws or certificate of designation that adversely affects the powers, preferences and rights of the Preferred Stock requires the approval of the holders of a majority of the shares of Preferred Stock then outstanding.
Dividends	The holders of our Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an as-if-converted-to-common-stock basis, without giving effect for such purposes to any beneficial ownership limitation) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors.
Common stock outstanding immediately before this offering	2,632,710 shares
Common stock outstanding immediately after this offering	3,857,198 shares or 4,040,871 shares if the underwriters exercise their over-allotment option in full.(1)(2)
Over-allotment option to be offered by us:	We have granted the underwriters the right to purchase up to 183,673 additional shares of common stock (or up to 184 additional shares of Preferred Stock) and/or warrants to purchase up to an aggregate of 137,755 shares of common stock at an exercise price of \$6.95 per share, in any combinations thereof, from us at the public offering price per security less the underwriting discounts and commissions within 45 days from the date of this prospectus to cover over-allotments. See “Underwriting” for additional information regarding the over-allotment option.
Use of proceeds	<p>We estimate that our net proceeds from this offering will be approximately \$5.1 million, based on the offering price of \$4.90 per share of common stock and accompanying warrant, or approximately \$5.9 million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discount and estimated offering expenses payable by us.</p> <p>We currently expect to use the net proceeds from this offering: (i) to cover expenses related to listing our shares on The NASDAQ Capital Market; (ii) to expand our sales leadership and field level sales resources; (iii) for research and development; (iv) to implement our Surface Acoustic Wave platform to other applications; (v) to pursue complimentary acquisitions; and (vi) for general working capital. Any balance of the net proceeds will be used for general corporate purposes. See “Use of Proceeds.”</p>

Dividend policy We have not declared or paid any cash or other dividends on our common stock or preferred stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future. See “Dividend Policy.”

Risk factors You should carefully read and consider the information beginning on page 9 of this prospectus set forth under the heading “Risk Factors” and all other information set forth in this prospectus before deciding to invest in our securities.

OTCQB symbol for common stock: NAOV.

Listing and NASDAQ Symbol: Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol “NAOV.” We do not intend to apply for any listing of the Preferred Stock on The NASDAQ Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect that the Preferred Stock will be quoted on the OTCQB over-the-counter marketplace. There is no established public trading market for the Preferred Stock, and we do not expect a market to develop.

- (1) Assumes only shares of common stock are sold in this offering and no exercise of the warrants issued in the offering. For each share of Preferred Stock purchased in this offering in lieu of common stock, we will reduce the number of shares of common stock being sold in the offering by 1,000.
- (2) Does not include an aggregate of 361,462 shares of common stock (or the corresponding number of shares of Preferred Stock in lieu of common stock, if applicable) we will be required to issue to the holders of the 2017 Notes upon closing of this offering, based on the outstanding principal amount and all accrued but unpaid interest on the 2017 Notes as of the expected closing date of this offering, at 80% of the offering price of \$4.90 per share of common stock and accompanying warrant.

The number of shares to be outstanding immediately before and immediately after this offering is based on 2,632,710 shares of our common stock and 1,951,261 shares of Series C Preferred Stock outstanding as of June 30, 2017, and excludes as of that date:

- 331,293 shares of common stock issuable upon the exercise of warrants with an exercise price of \$1.39 per share;
- 563,910 shares of common stock issuable upon the exercise of warrants with an exercise price of \$2.66 per share which were exercised into Series C Preferred Stock on October 4, 2017;
- 61,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$2.57 per share;
- 420,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$3.00 per share;
- 420,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$6.00 per share;
- 412,000 shares of common stock issuable upon the exercise of 2017 Warrants with an exercise price of \$5.90 per share;

- 1,951,261 shares of common stock issuable upon conversion of the currently outstanding Series C Preferred Stock;
- shares of common stock, or Preferred Stock in lieu of common stock, issuable upon conversion of the 2017 Notes.
- additional shares of common stock that maybe issued, upon exercise, to the holders of certain warrants to purchase an aggregate of 563,910 shares of common stock, pursuant to a full ratchet anti-dilution price protection in such warrants (See “Description of Securities — Warrants”); and
- 1,237,434 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from \$0.07 to \$120.75 and having a weighted average exercise price of \$3.87.

Unless otherwise stated, all information contained in this prospectus assumes:

- no investor purchased Preferred Stock in lieu of common stock sold in this offering;
- no exercise of warrants to purchase our common stock to be issued in this offering;
- no exercise of warrants to purchase common stock to be issued to the underwriters in connection with this offering; and
- no exercise of the over-allotment option granted to the underwriters.

Certain of our affiliates have indicated an interest in participating in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these affiliates may determine to purchase fewer securities than they have indicated an interest in purchasing or not to purchase any securities in this offering.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks described below, together with other information in this prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. Please also read carefully the section below entitled “Cautionary Note Regarding Forward-Looking Statements.”

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 six months ended June 30, 2017, we had a net loss of \$1,725,000, with revenues of \$104,000. For the fiscal year ended December 31, 2016, we had a net loss of \$2,831,000, with revenues of \$229,000. As of June 30, 2017, we had an accumulated deficit of \$25,142,000 and a total stockholders’ deficit of \$3,051,000. 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. Even if we succeed in commercializing our new products, we may not be able to generate sufficient revenues to cover our expenses and achieve profitability or be able to maintain profitability.

The report of our independent registered public accounting firm contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing. Further, the report of Kost Forer Gabbay & Kasierer, a member firm of Ernst & Young Global, our independent registered public accounting firm, with respect to our financial statements at December 31, 2016 and 2015 and for the two years ended December 31, 2016, includes an explanatory paragraph as to our potential inability to continue as a going concern. This may adversely affect our ability to obtain new financing on reasonable terms or at all.

If we are unable to raise additional capital, our clinical trials and product development will be limited and our long-term viability will be threatened; however, if we do raise additional capital, your percentage ownership as a stockholder could decrease and constraints could be placed on the operations of our business.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds of the sale of our securities, with only limited revenue being generated from our product sales. In order to fully realize our business objectives, we will need to raise additional capital following the completion of this offering. We will seek to raise such additional funds through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. These financings could result in substantial dilution to the holders of our common stock, or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations through the imposition of restrictive covenants and requiring us to pledge assets in order to secure repayment. In addition, if we raise funds through the sale of equity, we may issue equity securities with rights superior to our common stock, including voting rights, rights to proceeds upon our liquidation or sale, rights to dividends and rights to appoint board members. 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 lines through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

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

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

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

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

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

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

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

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

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

Our product candidates may not be developed or commercialized successfully.

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

We are subject to the risks that:

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Regulation of Our Products

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

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

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

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

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

- testing and quality control;

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

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

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

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

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

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

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

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

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

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

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

We cannot predict what additional healthcare reform initiatives may be adopted in the future or how federal and state legislative and regulatory developments are likely to evolve, but we expect ongoing initiatives in the United States to increase pressure on pricing for health care products and services. Such reforms could have an adverse effect on the pricing and market for our products.

If we fail to comply with the U.S. federal and state fraud and abuse and other health care laws and regulations, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which would have a material adverse effect on our business and results of operations.

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

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

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which also impose obligations and requirements on health care providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information.
- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children’s Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

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

Risks Related to our Operations in Israel

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

Our principal offices and manufacturing facilities are located in Israel and most of our officers and employees are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. During the summer of 2014, Israel was engaged in an armed conflict with Hamas in Gaza, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In addition, recent political uprisings and conflicts in various countries in the Middle East, including Egypt and Syria, are affecting the political stability of those countries. It is not clear how this instability will develop and how it will affect the political and security situation in the Middle East. This instability has raised concerns regarding security in the region and the potential for armed conflict. In addition, it is widely believed that Iran, which has previously threatened to attack Israel, has been stepping up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. Additionally, the Islamic State of Iraq and Levant (“ISIL”), a violent jihadist group, is involved in hostilities in Iraq and Syria. Although ISIL’s activities have not directly affected the political and economic conditions in Israel, ISIL’s stated purpose is to take control of the Middle East, including Israel. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy in general and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

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

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

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

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

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

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

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

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

Risks Related to Our Organization, and Our Common Stock, Warrants, Preferred Stock and this Offering

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 June 30, 2017, our directors, executive officers and 5% or greater stockholders and their respective affiliates beneficially owned in the aggregate approximately 57.5% of our voting capital stock. Upon the closing of this offering, our directors, executive officers and 5% or greater stockholders and their respective affiliates will beneficially own in the aggregate approximately % of our outstanding shares of common 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 “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.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase common stock and the associated warrant, or Preferred Stock and the associated warrants in lieu of common stock and the associated warrant, in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share of common stock after this offering. Based on the public offering price of \$4.90 per share of common stock and associated warrant, you will experience immediate dilution of approximately \$4.45 per share of common stock, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the offering price. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

You may experience additional dilution as a result of future equity offerings.

In order to raise additional capital, we have issued equity securities in the past and may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per unit in this offering. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be lower than the price per share paid by investors in this offering.

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

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

Notwithstanding anything in the 2017 Notes to the contrary, all of the holders of the 2017 Notes have agreed to convert the outstanding principal and accrued but unpaid interest on their 2017 Notes into shares of our capital stock and enter into 180 day lock-up agreements with respect to such securities issued upon conversion of the 2017 Notes in the event we consummate a Qualified Financing prior to December 31, 2017, pursuant to a firm commitment underwritten offering that results in our common stock being contemporaneously listed on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market or the Nasdaq Global Select Market, upon the closing date of such Qualified Offering.

This offering will constitute a Qualified Financing, and therefore, upon closing of this offering, based on the outstanding principal amount and all accrued but unpaid interest on the 2017 Notes as of the expected closing date of this offering, at 80% of the offering price of \$4.90 per share of common stock and accompanying warrant, we will be required to issue an aggregate of 361,461 shares of common stock and warrants to purchase an aggregate of 271,096 shares of common stock (or Preferred Stock and warrants, if applicable) to the holders of the 2017 Notes.

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

We may apply the proceeds of this offering to uses that ultimately do not improve our operating results or increase the value of your investment.

We intend to use the net proceeds of this offering to: (i) to cover expenses related to listing our shares on The NASDAQ Capital Market; (ii) to expand our sales leadership and field level sales resources; (iii) for research and development; (iv) to implement our Surface Acoustic Wave platform to other applications; (v) to pursue complimentary acquisitions; and (vi) for general working capital. Depending on several factors, including the availability of alternate sources of capital and the possibility that the execution or timing of our business plans may change, management may use these proceeds in a manner different than originally intended. These proceeds could be applied in ways that do not improve our operating results or otherwise increase the value of your investment.

Our common stock has been approved for listing on NASDAQ, however, if we cannot continue to satisfy the exchange's continuing listing criteria, NASDAQ may subsequently delist our common stock.

NASDAQ requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our common stock. Generally, we must maintain a minimum amount of stockholders equity and a minimum number of holders of our securities. If we fail to meet any of the continuing listing requirements, our common stock may be subject to delisting. If our common stock is delisted and we are not able to list our common stock on another national securities exchange, we expect our securities would be quoted on an over-the-counter market. If this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. There can be no assurance that an active trading market for our common stock will develop or be sustained.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Through our Israeli subsidiary, as of June 30, 2017, we received grants of \$492,000 from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the Office of the Chief Scientist, for research and development programs related to products that we are not currently commercializing or marketing. Because we are no longer developing the product to which the grants relate, we do not believe that we are subject to any material conditions with respect to the grants, except for the restrictions on our ability to make certain transfers of the technology or intellectual property related to these grants described below. We could in the future determine to apply for further grants. If we receive any such grants, we would have to comply with specified conditions, including paying royalties with respect to grants received. If we fail to comply with these conditions in the future, sanctions might be imposed on us, such as grants could be cancelled and we could be required to refund any payments previously received under these programs.

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

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

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

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

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

If you purchase Preferred Stock in lieu of common stock in this offering, as a holder of Preferred Stock, you will have no rights as a common stockholder with respect to the shares of common stock underlying the Preferred Stock until you acquire our common stock.

If you purchase Preferred Stock in lieu of common stock in this offering, until you acquire our common stock upon conversion of your Preferred Stock, you will have no rights with respect to the common stock underlying the Preferred Stock. Upon conversion of your Preferred Stock, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date for actions to be taken by our common stockholders occurs after the date you convert your Preferred Stock.

There is no public market for the Preferred Stock or the warrants to purchase shares of our common stock being offered by us in this offering and an active trading market for such stock is not expected to develop.

There is no established public trading market for the Preferred Stock or the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for any listing of the Preferred Stock or the warrants on The NASDAQ Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect that the Preferred Stock or the warrants will be quoted on the OTCQB over-the-counter marketplace. Without an active market, the liquidity of the Preferred Stock and the warrants will be limited.

The warrants are speculative in nature.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of \$6.95 per share, subject to certain adjustments, prior to the fifth anniversary of the date such warrants were issued, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants, if any, is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. The warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

Our Preferred Stock will rank junior to all our liabilities to third party creditors, and to any class or series of our capital stock created after this offering specifically ranking by its terms senior to the Preferred Stock, in the event of a bankruptcy, liquidation or winding up of our assets.

In the event of bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Preferred Stock only after all our liabilities have been paid. Our Preferred Stock will effectively rank junior to all existing and future liabilities held by third party creditors. The terms of our Preferred Stock do not restrict our ability to raise additional capital in the future through the issuance of debt. Our Preferred Stock will also rank junior to any class or series of our capital stock created after this offering specifically ranking by its terms senior to the Preferred Stock. In the event of bankruptcy, liquidation or winding up, there may not be sufficient assets remaining, after paying our liabilities, to pay amounts due on any or all of our Preferred Stock then outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 UroShield™.
- 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.
- Protection of 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. You should review carefully the section entitled “Risk Factors” beginning on page 9 of this prospectus for a discussion of these and other risks that relate to our business and investing in our securities. 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. The forward-looking statements contained in this prospectus are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the securities offered under this prospectus, after deducting the underwriting discount and estimated offering expenses payable by us, will be \$5.1 million. If the underwriters fully exercise the over-allotment option, the net proceeds from the sale of the securities offered under this prospectus, after deducting the underwriting discount and estimated offering expenses payable by us, will be \$5.9 million.

If all of the warrants sold in this offering were to be exercised in cash at the exercise price of \$6.95 per share, we would receive additional net proceeds of approximately \$6.4 million. We cannot predict when or if these warrants will be exercised. It is possible that these warrants may expire and may never be exercised.

We intend to use the net proceeds from this offering to: (i) to cover expenses related to listing our shares on The NASDAQ Capital Market; (ii) to expand our sales leadership and field level sales resources; (iii) for research and development; (iv) to implement our Surface Acoustic Wave platform to other applications; (v) to pursue complimentary acquisitions; and (vi) for general working capital. Any balance of the net proceeds will be used for general corporate purposes.

Investors are cautioned, however, that expenditures may vary substantially from these uses. Investors will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, the amount of competition we face and other operational factors. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

From time to time, we evaluate these and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized. Circumstances that may give rise to a change in the use of proceeds include:

- a change in development plan or strategy;
- the addition of new products or applications;
- technical delays;
- delays or difficulties with our clinical trials;
- negative results from our clinical trials;
- difficulty obtaining regulatory approval;
- failure to achieve sales as anticipated; and
- the availability of other sources of cash including cash flow from operations and new bank debt financing arrangements, if any.

Until we use the net proceeds of this offering, we will hold such funds in cash or invest the funds in short-term, investment grade, interest-bearing securities.

PRICE RANGE OF OUR COMMON STOCK

Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol “NAOV”.

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.

	Common Stock	
	High	Low
Fiscal Year Ending December 31, 2017		
Fourth quarter (through October 31, 2017)	\$ 7.32	\$ 6.75
Third quarter	\$ 6.75	\$ 5.50
Second quarter	\$ 6.25	\$ 5.80
First quarter	\$ 6.20	\$ 5.95
Fiscal Year Ended December 31, 2016		
Fourth quarter	\$ 7.00	\$ 5.50
Third quarter	\$ 5.56	\$ 5.20
Second quarter	\$ 5.50	\$ 4.75
First quarter	\$ 4.95	\$ 4.15
Fiscal Year Ended December 31, 2015		
Fourth quarter	\$ 4.86	\$ 4.20
Third quarter	\$ 4.25	\$ 3.50
Second quarter (from April 10, 2015 to June 30, 2015)	\$ 6.25	\$ 3.50

The last reported sale price for our common stock on the OTCQB as of October 31, 2017 was \$7.20 per share. As of October 31, 2017, we had 2,632,710 issued and outstanding shares of common stock, which were held by 120 holders of record.

As of October 31, 2017, we had a total of 2,310,256 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 or 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.

CAPITALIZATION

The following table summarizes our cash and cash equivalents, certain other items from our historical consolidated balance sheet, and capitalization as of June 30, 2017:

- on an actual basis; and
- on a pro forma as adjusted basis, (i) to give effect to the issuance of 265,613 shares of common stock and warrants to purchase an aggregate of 199,210 shares of common stock (assuming no Preferred Stock in lieu of common stock is issued) upon the closing of this offering as a result of the conversion of the 2017 Notes as of June 30, 2017 (assuming no Preferred Stock is issued upon conversion of the 2017 Notes), and (ii) to give further effect to our receipt of the net proceeds from the sale by us in this offering of shares of common stock at an offering price of \$4.90 per share and accompanying warrant (assuming (i) no Preferred Stock is issued upon conversion of the 2017 Notes, (ii) no exercise of warrants sold in this offering, and (iii) the accompanying warrants will be classified as equity instruments) and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors” sections above, as well as our audited and unaudited financial statements and the related notes appearing elsewhere in this prospectus.

	June 30, 2017 (in thousands) (unaudited)	
	Actual	Pro forma As Adjusted
Cash and cash equivalents	215	5,266
Long-Term Liabilities:		
Warrants to purchase common stock	1,948	1,948
Convertible promissory notes	713	-
Stockholders’ Deficiency:		
Common stock, par value \$0.001 per share – 20,000,000 shares authorized (actual) and 20,000,000 shares (pro forma as-adjusted); 2,632,710 shares issued and outstanding (actual) and 4,122,811 shares issued and outstanding (pro forma as-adjusted)	2	3
Preferred Stock, par value \$0.001 per share – 5,000,000 shares authorized (actual) and 5,000,000 shares (pro forma as-adjusted); 1,951,261 issued and outstanding (actual) and 1,951,261 shares issued and outstanding (pro forma as-adjusted)	2	2
Additional paid-in capital	22,087	27,850
Accumulated deficit	(25,142)	(25,142)
Total stockholders’ equity (deficiency)	(3,051)	2,713
Total Capitalization	(390)	4,661

The number of shares to be outstanding immediately before and immediately after this offering is based on 2,632,710 shares of our common stock and 1,951,261 shares of Series C Preferred Stock outstanding as of June 30, 2017, and excludes as of that date:

- 331,293 shares of common stock issuable upon the exercise of warrants with an exercise price of \$1.39 per share;
- 563,910 shares of common stock issuable upon the exercise of warrants with an exercise price of \$2.66 per share which were exercised into Series C Preferred Stock on October 4, 2017;
- 61,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$2.57 per share;
- 420,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$3.00 per share;
- 420,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$6.00 per share;
- 412,000 shares of common stock issuable upon the exercise of 2017 Warrants with an exercise price of \$5.90 per share;
- 1,951,261 shares of common stock issuable upon conversion of the currently outstanding Series C Preferred Stock;
- additional shares of common stock that maybe issued, upon exercise, to the holders of certain warrants to purchase an aggregate of 563,910 shares of common stock, pursuant to a full ratchet anti-dilution price protection in such warrants (See “Description of Securities — Warrants”);
- 1,237,434 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from \$0.07 to \$120.75 and having a weighted average exercise price of \$3.87;
- additional shares of common stock issuable upon the exercise of warrants to be issued to investors in this offering at an exercise price of \$6.95 per share; and
- additional shares of common stock issuable upon exercise of warrants to be issued to the underwriters in this offering at an exercise price of \$6.95 per share.

DILUTION

Our net tangible book value of our common stock as of June 30, 2017, was approximately \$(3,051,000), or approximately \$(0.67) per share of common stock and Preferred Stock (see note 1 below). “Net tangible book value” is total assets minus the sum of liabilities and intangible assets. “Net tangible book value per share” is net tangible book value divided by the total number of shares outstanding.

After giving effect to (i) the issuance of 265,613 shares of common stock and warrants to purchase an aggregate of 199,210 shares of common stock (assuming no Preferred Stock in lieu of common stock is issued) upon the closing of this offering as a result of the conversion of the 2017 Notes as of June 30, 2017 (assuming no Preferred Stock is issued upon conversion of the 2017 Notes), and (ii) the sale of shares of common stock (assuming no Preferred Stock is issued upon conversion of the 2017 Notes) at an offering price of \$4.90 per share and accompanying warrant and after deducting the underwriting discount and estimated offering expenses payable by us, our net tangible book value as of June 30, 2017, would have been approximately \$2,712,990, or approximately \$0.45 per share of common and preferred (see note 1 below) stocks based on shares of common and preferred stocks outstanding on an as adjusted basis at that time of the offering. This represents an immediate increase in net tangible book value of \$1.11 per share to our existing stockholders and an immediate dilution of approximately \$4.45 per share to new investors participating in this offering, as illustrated by the following table:

Public offering price per share of common stock and accompanying warrant	\$	4.90
Net tangible book value per share of common and preferred stock as of June 30, 2017	\$	(0.67)
Increase in net tangible book value per share of common stock attributable to the offering and the conversion of convertible promissory notes	\$	<u>1.11</u>
As adjusted net tangible book value per share of common stock as of June 30, 2017 after giving effect to the offering	\$	<u>0.45</u>
Dilution in net tangible book value per share of common stock to new investors in the offering	\$	<u>4.45</u>

The discussion of dilution, and the table quantifying it, assumes no exercise of any outstanding options or warrants or other potentially dilutive securities. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

In particular, the table above excludes the following potentially dilutive securities as of June 30, 2017:

- 331,293 shares of common stock issuable upon the exercise of warrants with an exercise price of \$1.39 per share;
- 563,910 shares of common stock issuable upon the exercise of warrants with an exercise price of \$2.66 per share which were exercised into Series C Preferred Stock on October 4, 2017;
- 61,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$2.57 per share;
- 420,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$3.00 per share;
- 420,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$6.00 per share;
- 412,000 shares of common stock issuable upon the exercise of 2017 Warrants with an exercise price of \$5.90 per share;
- additional shares of common stock that maybe issued, upon exercise, to the holders of certain warrants to purchase an aggregate of 563,910 shares of common stock, pursuant to a full ratchet anti-dilution price protection in such warrants (See “Description of Securities — Warrants”);
- 1,237,434 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from \$0.07 to \$120.75 and having a weighted average exercise price of \$3.87;
- additional shares of common stock issuable upon the exercise of warrants to be issued to investors in this offering at an exercise price of \$6.95 per share; and
- additional shares of common stock issuable upon exercise of warrants to be issued to the underwriters in this offering at an exercise price of \$6.95 per share.

To the extent that any of these options are exercised, new options are issued under our equity incentive plans and subsequently exercised or we issue additional shares of common stock in the future, there will be further dilution to new investors participating in this offering.

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the as adjusted net tangible book value will increase to \$0.58 per share, representing an immediate dilution of \$4.32 per share to new investors.

(1) Preferred stock participates equally with shares of common stock in our profits, losses and liquidation values.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

You should read the following discussion and analysis of financial condition and results of operations in conjunction with our financial statements and the related notes thereto included elsewhere in this prospectus. 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 "Risk Factors" and elsewhere in this prospectus. See "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this prospectus.

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

Since March 1, 2017, we have completed a series of bridge financings pursuant to which we have received aggregate proceeds of \$1,380,000 in exchange for convertible promissory notes in the aggregate principal amount of \$1,380,000, and seven-year warrants to purchase an aggregate of 552,000 shares of common stock at an exercise price of \$5.90 per share.

The principal amount and all accrued but unpaid interest on each 2017 Note will become due and payable on the earlier of the (i) 5-year anniversary of the date of issuance, or (ii) the date we complete a Qualified Financing, which is an equity financing pursuant to which we issue and sell shares of capital stock resulting in aggregate proceeds of at least \$2,000,000. The 2017 Notes bear interest at a rate of 6% per annum.

Notwithstanding anything in the 2017 Notes to the contrary, all of the holders of the 2017 Notes have agreed to convert the outstanding principal and accrued but unpaid interest on their 2017 Notes into shares of our capital stock and enter into 180 day lock-up agreements with respect to such securities issued upon conversion of the 2017 Notes in the event we consummate a Qualified Financing prior to December 31, 2017, pursuant to a firm commitment underwritten offering that results in our common stock being contemporaneously listed on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market or the Nasdaq Global Select Market, upon the closing date of such Qualified Offering.

This offering will constitute a Qualified Financing, and therefore, upon closing of this offering, based on the outstanding principal amount and all accrued but unpaid interest on the 2017 Notes as of the expected closing date of this offering, at 80% of the offering price of \$4.90 per share of common stock and accompanying warrant, we will be required to issue an aggregate of 361,462 shares of common stock and warrants to purchase an aggregate of 271,096 shares of common stock (or Preferred Stock and warrants, if applicable) to the holders of the 2017 Notes, all of which will be subject to lock-up agreements for 180 days. Dawson James Securities, Inc. may, in its sole discretion, upon prior written consent, release all or any portion of the shares subject to the lock-up agreements.

In the absence of a Qualified Financing, on the maturity date, the holders of our 2017 Notes may elect to have the outstanding principal and accrued but unpaid interest thereon repaid in cash or converted into common stock. To the extent that the conversion of our 2017 Notes causes any holder thereof to beneficially own more than 9.99% of our common stock, such holder may elect to receive shares of our Series C Convertible Preferred Stock (the "Series C Preferred Stock") in lieu of common stock or common stock equivalents. If there is a change of control and the 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 2017 Notes and interest then accrued and unpaid thereon, or (b) convert the 2017 Notes and all accrued and unpaid interest thereon into shares of common stock or Series C Preferred Stock 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) our estimated value implied by the exchange ratio set forth in the agreement governing such change of control transaction, as determined in good faith by our board of directors, by (ii) the aggregate number of outstanding shares of common stock, as calculated on a fully diluted basis, and (y) \$5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting our capital stock.

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, our functional and reporting currency is the U.S. dollar.

Our 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 our 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 our 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 our 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 (unless the warrants do not include a down-round protection mechanism, and are then measured at fair value at inception only and classified as equity instruments). The remaining proceeds are allocated among all other freestanding instruments (embedded beneficial conversion feature, if applicable, 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 of instruments which bear such feature, 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 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, due to their anti-dilution protections, 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 our 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.

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

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Non-public Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception*. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II simply replaces the indefinite deferral for certain mandatorily redeemable non-controlling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification (ASC) Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. This ASU is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of the standard may have on its consolidated financial statements.

Extended Transition Period for "Emerging Growth Companies"

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

Going Concern

The financial statements have been prepared assuming that we will continue as a going concern. Since our formation, we utilized funds generated from private placement offerings and debt to fund our product development. We incurred losses in the amount of \$2,831,000 during the year ended December 31, 2016. As of June 30, 2017, we had an accumulated deficit of \$25,142,000 and a total stockholders' deficit of \$3,051,000. The recurring losses from operations and current liquidity raise substantial doubt about our ability to continue as a going concern. Our continuation is dependent on obtaining additional financing.

Results of Operations

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

Revenues. For the six months ended June 30, 2017 and 2016, our revenues were approximately \$104,000 and \$119,000, respectively, a decrease of approximately 12.6%, or \$15,000, between the periods. The decrease was mainly attributable to decreased sales to consumers in the six months ended June 30, 2017. Our revenues may fluctuate as we add new consumers or when existing distributors or consumers make large purchases of our products during one period and no purchases during another period. Our revenues may fluctuate from quarter-to-quarter and any growth or decrease in revenues by quarter may not be linear or consistent.

For the six months ended June 30, 2017, the percentage of revenues attributable to our products was: PainShield - 93% and UroShield - 7%. For the six months ended June 30, 2016, the percentage of revenues attributable to our products was: PainShield - 93% and UroShield - 7%. For the six months ended June 30, 2017 and 2016, the percentage of revenues attributable to our disposable products was 42% and 48%, respectively. For the six months ended June 30, 2017 and 2016, the portion of our revenues that was derived from distributors was 36% and 33%, respectively.

Gross Profit. For the six months ended June 30, 2017 and 2016, gross profit remained unchanged at approximately \$70,000. Gross profit for the six months ended June 30, 2017 remained unchanged from the same period in 2016 despite lower revenues due to a markdown of obsolete inventory during such period in 2016.

Gross profit as a percentage of revenues was approximately 67% and 59% for the six months ended June 30, 2017 and 2016, respectively. The increase in gross profit as a percentage is mainly due to the markdown of obsolete inventory as described above.

Research and Development Expenses. For the six months ended June 30, 2017 and 2016, research and development expenses were approximately \$314,000 and \$287,000, respectively, an increase of approximately 9%, or \$27,000, between the periods. The increase was primarily due to the increase in expenses related to our clinical trials.

Research and development expenses as a percentage of total revenues were approximately 302% and 241% for the six months ended June 30, 2017 and 2016, respectively. The increase was due primarily to the increase in expenses described above.

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 application and registration, clinical trial and facilities expenses associated with and allocated to research and development activities.

Selling and Marketing Expenses. For the six months ended June 30, 2017 and 2016, selling and marketing expenses were approximately \$200,000 and \$271,000, respectively, a decrease of approximately 26%, or \$71,000, between the periods. The decrease was mainly due to a decrease in our sales staff and to a lesser degree decreased selling and marketing activities, particularly trade show expenses and marketing campaigns as we had to reduce our sales budget due to limited cash resources.

Selling and marketing expenses as a percentage of total revenues were approximately 192% and 228% for the six months ended June 30, 2017 and 2016, respectively. The decrease was due primarily to the decrease in expenses described above.

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

General and Administrative Expenses. For the six months ended June 30, 2017 and 2016, general and administrative expenses were approximately \$1,017,000 and \$442,000, respectively, an increase of approximately 130%, or \$575,000, between the periods. The increase was mainly due to a \$415,000 increase in our stock based compensation and to a lesser degree the increased compensation costs of the new management team hired in the fourth quarter of 2016.

General and administrative expenses as a percentage of total revenues were approximately 978% and 371% for the six months ended June 30, 2017 and 2016, respectively. The increase was due primarily to the increase in expenses described above.

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

Financial Expenses, net. For the six months ended June 30, 2017 and 2016, financial expenses, net were approximately \$242,000 and \$156,000, respectively, an increase of approximately 55%, or \$86,000, between the periods. The increase resulted primarily an additional expense of approximately \$320,000 related to the issuance of the Warrants amortized over the expected life of the 2017 Notes issued in the first two quarters of 2017 offset by a \$131,000 reduction due to a lower valuation adjustment of our warrants that were issued with our 2013 and 2015 convertible promissory notes.

Tax expenses. For the six months ended June 30, 2017 and 2016, tax expenses were \$22,000 and \$19,000, respectively. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate. The increase in our tax expenses was due to increased spending by our Israel subsidiary.

Loss. Our loss increased by approximately \$620,000, or 56%, to approximately \$1,725,000 for the six months ended June 30, 2017 from approximately \$1,105,000 in the same period of 2016. The increase in net loss resulted primarily from the factors described above.

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

Revenues. For the three months ended June 30, 2017 and 2016, our revenues were approximately \$52,000 and \$62,000, respectively, a decrease of approximately 16%, or \$10,000, between the periods. The decrease was mainly attributable to decreased sales to our consumers in the three months ended June 30, 2017. Our revenues may fluctuate as we add new consumers or distributors or when existing consumers or distributors make large purchases of our products during one period and no purchases during another period. Our revenues may fluctuate from quarter-to-quarter and any growth or decrease in revenues by quarter may not be linear or consistent.

For the three months ended June 30, 2017, the percentage of revenues attributable to our products was: PainShield - 92% and UroShield - 8%. For the three months ended June 30, 2016, the percentage of revenues attributable to our products was: PainShield - 90% and UroShield - 10%. For the three months ended June 30, 2017 and 2016, the percentage of revenues attributable to our disposable products was 46% and 41%, respectively. For the three months ended June 30, 2017 and 2016, the portion of our revenues that was derived from distributors was 37% and 27%, respectively.

Gross Profit. For the three months ended June 30, 2017, gross profit decreased by approximately 15%, or \$6,000, to approximately \$34,000 from approximately \$40,000 during the same period in 2016. The decrease was due lower sales as well as a shift in higher sales of products sold through distributors that typically carry lower gross margins.

Gross profit as a percentage of revenues was approximately 67% and 65% for the three months ended June 30, 2017 and 2016, respectively. The increase in gross profit as a percentage is mainly due to the increased percentage of higher margin sales described above.

Research and Development Expenses. For the three months ended June 30, 2017 and 2016, research and development expenses were approximately \$164,000 and \$173,000, respectively, a decrease of approximately 5%, or \$9,000, between the periods. The decrease was primarily due to a small decrease in expenses related to our clinical trials.

Research and development expenses as a percentage of total revenues were approximately 315% and 279% for the three months ended June 30, 2017 and 2016, respectively. The increase was due to the decrease in revenues.

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 application and registration, clinical trial and facilities expenses associated with and allocated to research and development activities.

Selling and Marketing Expenses. For the three months ended June 30, 2017 and 2016, selling and marketing expenses were approximately \$106,000 and \$126,000, respectively, a decrease of approximately 16%, or \$20,000, between the periods. The decrease was mainly due to a decrease in our sales staff and to a lesser degree decreased selling and marketing activities, particularly marketing expenses as we had to reduce our sales budget due to limited cash resources.

Selling and marketing expenses as a percentage of total revenues remained relatively unchanged and were approximately 204% and 203% for the three months ended June 30, 2017 and 2016, respectively.

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 three months ended June 30, 2017 and 2016, general and administrative expenses were approximately \$424,000 and \$197,000, respectively, an increase of approximately 115%, or \$227,000, between the periods. The increase was mainly due to the increased compensation costs of the new management team hired in the fourth quarter of 2016 including their stock based compensation.

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

Financial Expenses, net. For the three months ended June 30, 2017 and 2016, financial expenses, net were approximately \$178,000 and \$144,000, respectively, an increase of approximately 24%, or \$34,000, between the periods. The increase resulted from additional expenses incurred from the issuance of the Warrants amortized over the expected life of the 2017 Notes issued in the first two quarters of 2017 offset by a reduction derived by a lower valuation adjustment of our warrants that were issued with our 2013 and 2015 convertible promissory notes.

Tax expenses. For the three months ended June 30, 2017 and 2016, tax expenses remained unchanged at \$11,000 and \$10,000, respectively. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate. The increase in our tax expenses was due to increased spending by our Israel subsidiary.

Loss. Our net loss increased by approximately \$239,000, or 39%, to approximately \$849,000 for the three months ended June 30, 2017 from approximately \$610,000 in the same period of 2016. The increase in net loss resulted primarily from the factors described above.

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 foreseeable 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 distributors and sales directly to the end customers (where sales directly to the end customers generally have a higher margin). As a result, we are subject to year-over-year fluctuation in our gross profits.

Research and Development Expenses. For the twelve months ended December 31, 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 continue to incur losses and negative cash flows from operating activities. We have incurred losses in the amount of \$1,725,000 during the six month period ended June 30, 2017, and have accumulated negative cash flow from operating activities of \$919,000 for the six month period ended June 30, 2017. For the twelve months ended December 31, 2016, we 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. As of June 30, 2017, we had an accumulated deficit of \$25,142,000 and a total stockholders' deficit of \$3,051,000. 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. We will need to raise additional capital to finance our 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 August 14, 2017, we met our short-term liquidity requirements from our existing cash reserves and bridge financings of \$1,030,000. We intend to use the proceeds of the offering to which this prospectus relates to meet such short-terms requirements as well as to advance our long-term plans. It is our current belief that the proceeds of this offering will provide sufficient funding to meet our liquidity needs for more than a year.

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 June 30, 2017, and we are not aware of any material trends in capital resources that would impact our business.

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

General. As of June 30, 2017, we had cash and cash equivalents of approximately \$215,000, compared to approximately \$106,000 as of December 31, 2016. The decrease is attributable primarily to our net cash used in operating activities. 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, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately \$919,000 for the six months ended June 30, 2017 and \$840,000 for the same period in 2016. The increase in our cash usage was mainly associated with the increase in our net operating loss for the six months ended June 30, 2017 compared to the three months ended June 30, 2016, for the reasons described above.

Cash used in investing activities was \$2,000 and \$8,000 for the six month periods ended June 30, 2017 and 2016, respectively, and was related to purchases of fixed assets.

Cash provided by financing activities was approximately \$1,030,000 for the six months ended June 30, 2017 derived from proceeds received from the issuance of 2017 Notes and \$33,000 for the six months ended June 30, 2016, which was derived from proceeds from the exercise of certain options.

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 June 30, 2017, we have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

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.

BUSINESS

Overview

We were organized as a Delaware corporation in October 2003. Through our wholly-owned subsidiary, NanoVibronix Ltd., a private company incorporated under the laws of the State of Israel, we focus on noninvasive biological response-activating devices that target biofilm prevention, wound healing and pain therapy and can be administered at home, without the assistance of medical professionals. In 2016, we were one of the companies selected by the Israeli government to present at its “Israeli Innovation and Technologies in Africa and Developing Countries” conference. Our primary products, which are in various stages of clinical and market development, currently consist of:

- UroShield™, an ultrasound-based product that is designed to prevent bacterial colonization and biofilm in urinary catheters, increase antibiotic efficacy and decrease pain and discomfort associated with urinary catheter use.
- PainShield™, a patch-based therapeutic ultrasound technology to treat pain, muscle spasm and joint contractures by delivering a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area; and
- WoundShield™, a patch-based therapeutic ultrasound device intended to facilitate tissue regeneration and wound healing by using ultrasound to increase local capillary perfusion and tissue oxygenation.

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

PainShield is currently cleared for marketing in the United States by the U.S. Food and Drug Administration although there has not been a significant sales and marketing effort to date. 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 have consummated sales of PainShield and UroShield in the relevant markets, although to date sales have been minimal; WoundShield has not generated significant revenue to date. Outside of the United States we generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

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

In addition to the need to obtain regulatory approvals, we anticipate that sales volumes and prices of our UroShield, PainShield, and WoundShield products will depend in large part on the availability of insurance coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid in the United States, private insurance plans and workers' compensation plans. We do not currently have reimbursement codes for use of WoundShield in any of the markets in which we have regulatory authority to sell WoundShield. Of the markets in which we have regulatory authority to sell PainShield, we have reimbursement codes in the United States (i.e., CPT codes) for clinical use only, but do not have such reimbursement codes for at-home use of the product, although the product is marketed and sold for such use. With respect to UroShield, which may be used in a clinical and home setting, we do not currently have reimbursement codes in any of the markets in which we have regulatory authority to sell UroShield. We anticipate that we will begin to seek reimbursement codes for use of our products in the markets in which we have regulatory authority to sell such products; however, additional clinical data will be required in order to obtain such reimbursement codes. Our current ongoing research and planned research may facilitate our ability to obtain reimbursement codes and there is no guarantee that we will be successful in obtaining such codes quickly, or at all.

We have completed 5 separate clinical studies with UroShield that together evaluated approximately 139 patients with urinary catheters. In patients where the UroShield product was used there were no serious adverse events reported, while a variety of clinical beneficial observations were seen including: catheter biofilm reduction, reduction in catheter associated pain, reduction in urinary tract infections, and a significant decrease in bacteriuria rates. We are currently conducting a double blind clinical trial for UroShield in the United States in order to obtain 510(k) clearance from the U.S. Food and Drug Administration. In July 2017, we engaged Idonea Solutions, Inc., an FDA consultant, to assist in our efforts. If we are able to successfully obtain 510(k) clearance, we intend to pursue obtaining reimbursement codes and to target completion of partnerships with leading catheter product companies for sales and marketing efforts in the United States.

In addition, we are currently ramping up our clinical development and marketing efforts in North America with respect to PainShield. We are currently conducting a clinical trial to evaluate the effect of PainShield in patients with trigeminal neuralgia. We believe that a positive outcome in this trial will assist in our expanding the commercial use of this product through a direct sales effort that we intend to manage. We have also identified a market for PainShield in the professional sports industry, where in some cases reimbursement may be available from sports alumni organizations or, more likely, self-pay. In order to pursue this market, we are exhibiting at sports trainers meetings, pursuing alumni associations, advertising in their media, and negotiating with a sports trainer focused sales organization. The PainShield device is offered for sale to practitioners with a provider rental program which was implemented in January 2017. The PainShield product was also modified and enhanced through various accessories for use within the equine community. This market is currently being pursued through prominent equine clinicians and independent sales representatives and distributors. 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. We are pursuing appropriate distributors in the U.S. market with resources and qualifications to sell PainShield in the different segments of the pain treatment market.

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

Business Model

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

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

Ultrasound Technology and Our Products

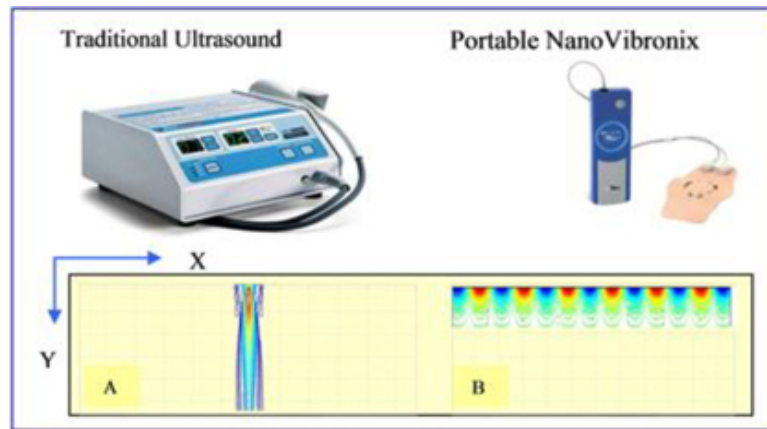
As noted above, our primary products are based on the use of low frequency ultrasound, which delivers energy through mechanical vibrations in the form of sound waves. Ultrasound has long been used in physical therapy, physical medicine, rehabilitation and sports medicine. Moreover, there is a growing body of research that supports the positive biological effects of ultrasound. A 2002 study 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 (Atland 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 offers the benefits cited above by increasing local blood circulation, increasing vascular wall permeability, promoting protein secretion, promoting enzymatic reactions, accelerating nitric oxide production, promoting angiogenesis (the formation of new blood vessels from pre-existing vessels) and promoting fibroblast proliferation (fibroblasts are a type of cell that play a critical role in wound healing). We believe that the body of evidence, and the positive therapeutic effect that ultrasound has for various indications, potentially provides for future product development opportunities for us.

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

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



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

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

Micro Vibrations Technology and Our Products

It is well established that increasing blood flow to the wound and peri-wound area helps accelerate the healing of ischemic wounds. Micro-vibrations applied on the skin tissue increase local blood flow and oxygen delivery to the wound area and stimulate angiogenesis and growth factors that are helpful for the wound healing process. Vibration therapy has been found to stimulate blood flow due to mechanical stresses of endothelial cells resulting in increased production of nitric oxide and vasodilation, as well as increase soft tissue and skin circulation (Maloney-Hinds et al., “The Role of Nitric Oxide in Skin Blood Flow Increases due to vibration in healthy adults and adults with type 2 diabetes,” School of Medicine, Loma Linda University. Ca. Diabetes Technology & Therapeutics, 2009 p. 39-43). In addition, micro vibrations induce skin surface nerve axon reflex and type IIa muscle fibers contraction rates, resulting in vasodilation (Nakagami et al., “Effect of vibration on skin blood flow in an in vivo microcirculatory model”, The University of Tokyo, Bio-Science Trends 2007; 1 (3): 161-166). Ten minutes of vibration therapy with laser doppler revealed a consistent increase in water content of the upper dermis 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- $\kappa\beta$, the key gene for inflammatory mediators (Sackner, M.A., “Nitric Oxide is released into circulation with whole-body, periodic acceleration”, Chest 2005;127;30-39).

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

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

Our Products

UroShield

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



Picture of UroShield with actuator

The UroShield system has the following advantageous effects:

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

- **Decreased Catheter Associated Pain and Discomfort.** We believe that UroShield creates an acoustic envelope on the surfaces of the catheter, which decreases friction and tissue trauma, pain and discomfort caused by the catheter. In addition, in vivo (rabbit) studies have shown the tissue in contact with the catheter remains healthier and less traumatized as a result of the application of low frequency and low intensity ultrasound (Applebaum I, et.al., “The Effect of Acoustic Energy Induced By UroShield on Foley Catheter Related Trauma and Inflammation in a Rabbit Model” Department of Urology, Shaarey Zedek Medical Center and the Hadassah Hebrew University Medical School).
- **Acoustically Augmented Antibiotic Therapy.** Antibiotic resistance in biofilm bacteria is a well-known phenomenon. Although it has been known that ultrasound can increase antibiotic efficacy in in-vitro models, we do not believe that there has been a practical ultrasound-based medical device that was able to augment antibiotic efficacy in the clinical setting. In a clinical study, UroShield technology has been shown to eradicate biofilm-residing bacteria by greater than 85% when applied simultaneously with an antibiotic in three clinically relevant species, escherichia coli, staphylococcus epidermidis and pseudomonas aeruginosa (Banin E, et al., “Surface acoustic waves increase the susceptibility of Pseudomonas aeruginosa biofilms to antibiotic treatment,” Biofouling, August 2011; we supplied devices for this study, but had no further involvement with it).
- **Preservation of the Patency of Catheters.** We believe that low frequency ultrasound applied to catheters will add an anti-clogging effect and will preserve patency of catheters. This effect is achieved by ultrasound waves creating an acoustic layer on the inner lumen of the urinary catheter, thereby preventing adherence of biological material and biofilm formation. We believe that this anti-clogging benefit will help prevent local infection and sepsis secondary to catheter obstruction.

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

In a subsequent physician-sponsored trial known as Heidelberg 2, 40 patients who underwent radical prostatectomies were divided into two groups, with the active group receiving one intra-operative dose of antibiotics and UroShield and the control group receiving one intra-operative dose of antibiotics and then five subsequent doses over three days. At the end of the trial, the control group had four cases of 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 katheterassozierten Harnwegsinfektionen?,” Gesellschaft für Urologie, Heilbronn, Germany, May 2008). We supplied devices for this trial, but had no further involvement with it.

Market for UroShield

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

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

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

According to a report by Zion Market Research, the global catheter market totaled approximately \$26.6 billion in 2015 and is estimated to grow at a CAGR of 9.7% through 2021. In the United States there are 25 million Foley catheters sold annually and there are 75 million catheters sold elsewhere yielding a total global Foley catheter market of 100 million units worldwide. The cost to treat a simple CAUTI has been estimated at \$675 per case, and the cost of treating bacteremia has been estimated at \$3,800 per case, yielding a total healthcare burden of \$830 million per year. While there are currently both antibiotic and silver coated catheters in the market, they often sell for approximately \$10 above the non-antimicrobial equivalent.

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

Competition for UroShield

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

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

Regulatory Strategy

UroShield received CE Mark approval in September 2007 and was also approved for sale by the Israeli Ministry of Health in 2008. We are able to sell UroShield in India and Ecuador based on our CE Mark. UroShield was granted a Canadian medical device license in September 2016.

In the European Union, UroShield has been marketed for the prevention of biofilm, decreased pain and discomfort associated with urinary catheters and increased antibiotic efficacy. In the United States, we intend to seek clearance from the U.S. Food and Drug Administration through the de novo classification process for UroShield. We submitted our application for 510(k) 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 60 patients in a randomized controlled trial. This ongoing study has been approved by the institutional review board, or IRB, and is currently enrolling patients within two nursing homes 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 U.S. dollars to the extent that UroShield obtains 510(k) clearance from the U.S. Food and Drug Administration, is recognized as effective and becomes widely adopted for use in catheters. To that end, we are exploring sales distribution models in the United States through a distributor network and direct sales. In order to have a distribution network in place if UroShield receives clearance from the U.S. Food and Drug Administration, we are currently identifying distributors through several vehicles, including our sales staff, commissionable representation, and independent contractors.

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

Clinical Trials

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

Purpose	Doctor/Location	Time, subjects	Objectives	Results
To assess the safety of the UroShield Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD1)	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2005-2006 22 patients	To demonstrate that the use of the UroShield is safe and that the device is well tolerated by the patients and user friendly to the medical staff. Efficacy objectives were to demonstrate that the UroShield helps in prevention of biofilm formation in comparison with the urinary catheter alone, as well as bacteriuria.	UroShield was both safe and well tolerated. UroShield proved efficacious in prevention of biofilm. Subjects required significantly less medications than the control group for catheter related pain and discomfort.
Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD2) Physician initiated	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2007 40 patients	To demonstrate that the use of the UroShield is safe and helps in prevention of biofilm formation and UTI in comparison with the urinary catheter alone, as well as decrease antibiotic use.	In this trial, only 1/20 patients in UroShield device (no antibiotics) group developed urinary tract infection compared to 4/20 patients within control group treated with the antibiotic prophylaxis alone.

The Effect of UroShield on Pain and Discomfort in Patients Released from the Emergency Room with Urinary Catheter Due to Urine Incontinence Physician initiated	Shaare Zedek Medical Center Jerusalem, Israel.	2007 10 patients	The study aimed to assess the effectiveness of the UroShield in reducing pain and discomfort levels and improve the well-being of the subjects. Efficacy objectives included reduction of pain, spasm, burning and itching sensation levels of the subjects.	The results demonstrated a reduction in pain, itching, burning and spasm levels. Additionally, the well-being of the subjects showed a significant increase.
The Use of the UroShield Device in Patients with Indwelling Urinary Catheters Open labeled, comparative, randomized study	Dr. Shenfeld Shaare Zedek Medical Center Jerusalem, Israel.	2007-2009 40 patients	Patient complaints related to catheter regarding pain according to VAS scale and discomfort according to 0-10 scale Presence of Clinically Significant UTI Presence of Bacteriuria Presence of Biofilm Use of medication	UroShield device was effective in reducing postoperative catheter related pain discomfort and bladder spasms. There was also a notable trend towards reduction of bacteriuria.
Evaluation of the UroShield in urinary and nephrostomies to reduce bacteriuria Physician initiated	Prof. P.Tenke, Hungary	2010-2011 27 patients	<ul style="list-style-type: none"> ● Pain, disability and QOL ● Catheter patency ● Bacteriuria / UTI ● Hospitalization period ● Analgesics and Antibiotics intake 	Showed reduction in pain and significant decrease in bacteriuria rate.

Current, Ongoing and Planned Clinical Trial

Study Currently Enrolling-Prevention of Bacterial Colonization and Pain associated with Indwelling Urinary Catheters. (60 Patients)

- RCT examining the efficacy for the prevention of bacterial colonization and pain related to indwelling catheters.

Interim Results:

Trial

- 22 subjects evaluated at two skilled nursing facilities near Buffalo, NY
 - 11 patients treated with placebo devices (“controlled”)
 - 11 patients had active UroShield devices (“treatment”)
 - All exhibited significant colonization of multiple microorganisms in both the catheter device as well as retained urine from the bladder
- Most counted at greater than 100,000 colony forming unit (CFUs)

30-Day evaluation results

- All 11 subjects in controlled group still exhibited greater than 100,000 CFUs
 - All 11 subjects in UroShield treatment group exhibited reductions in CFUs
- Most measured less than 10,000 CFUs
Many measured less than 1,000 CFUs; a greater than 90% reduction

60-Day Follow-Up

- 2 of 11 subjects in controlled group developed a clinical infection
- None of the subjects in UroShield treatment group developed a clinical infection

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	<p>Safety and efficacy of UroShield in urinary catheter related pain and infection and biofilm formation.</p> <p>The results of previous clinical trials may not be predictive of future results, and the results of our planned clinical trial, if we are able to locate a strategic partner or otherwise obtain sufficient funding, may not satisfy the requirements of the FDA</p>

PainShield®

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

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



Picture of PainShield with Patch

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

Market for PainShield

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

Competition

There are numerous products and approaches currently utilized to treat chronic pain. The pharmacological approach, which may be the most common, focuses on drug-related treatments with the over-the-counter internal analgesic market estimated at \$3.8 billion in 2013. Alternatively, there are a large number of non-pharmacological pain treatment options available, such as ultrasound, transcutaneous electrical nerve stimulation, or TENS, laser therapy and pulsed electromagnetic treatment. In addition, there are some technologies and devices in the market that utilize low frequency ultrasound or patch technology. Many patients are initially prescribed anti-pain medication; however, ongoing use of drugs may cause substantial side effects and lead to addiction. Therefore, patients and clinicians have shown increased interest in alternative pain therapy using medical devices that do not carry these side effects.

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

Regulatory Strategy

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

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

Sales and Marketing

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

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

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

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

Ongoing Research

A double blind randomized control trial of a Painshield Surface Acoustic Wave Patch, the patch used in conjunction with the PainShield 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 end of 2017 or early 2018.

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.

To date, 26 patients have been evaluated as fully completing the study. Results from these patients showed a greater than 3 point difference in pain measured by the Visual Analog Scale between the active treatment group and the control group. This was further validated in the crossover group from sham to active groups. Patients also showed quality of life by greater than 35% in the treatment group versus the control group, which was validated in the crossover group.

Clinical Trials

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

Purpose	Doctor/Location	Time, subjects	Objectives	Results
A sound solution for Trigeminal Neuralgia Physician initiated	Dr. Ch. Adahan Sheba Medical Center	2009 15 patients	<ul style="list-style-type: none"> ●Reduction in pain ●Reduction in disability ●Improvement of function and quality of life ●Accelerating of healing 	73% of the subjects experienced complete or near complete relief.
Randomized control trial examining the efficacy of low intensity low frequency Surface Acoustic wave ultrasound in trigeminal neuralgia pain For Ph.D., Funded by Israeli Ministry of Health	Dr. M. Zwecker Chaim Sheba Medical Center, Tel Hashomer, Israel	2012-2012 16 patients	<ul style="list-style-type: none"> ●Reduction in pain ●Reduction in disability ●Improvement of function and quality of life ●Accelerating of healing 	In conclusion this study supports the hypothesis that the application of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound (LILF/SAW) may be associated with a clinically significant reduction of pain severity among patients suffering from trigeminal neuralgia disease.
Treating Rutgers university athletic injuries with bandaid sized ultrasound unit PainShield	R. Monaco, G. Sherman, Rutgers University Athletic, Rutgers, New Jersey	2011 35 patients	<ul style="list-style-type: none"> ●To assess the pain, functional capacity and discomfort of the subject ●To assess the subject's quality of life ●To assess the injury status ●To assess the efficacy of the treatment ●To assess compliance factors 	Active group: 74% had improvement, 26% no change Sham group: 56% no change, 44% had improvement This is an indication of the effectiveness of the device. Lack of funding for statistical analysis has stopped this trial prior to fulfillment.

Reduction of chronic abdominal and pelvic pain, urological and GI symptoms using wearable device delivering low frequency ultrasound	D. Wiseman, Synechion Institute for Pelvic Pain	2011 19 patients	●To assess the efficacy of PainShield for pelvic and related pain	Improvement in pain related symptoms noted for all symptoms.
PainShield for Trigeminal Neuralgia 60 patient trial	Shira Markowitz, MD, New York, NY	Start date: November 2016 Expected completion: End of 2017 or early 2018	●To assess the efficacy of PainShield for treating trigeminal neuralgia	

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

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

WoundShield®

Our WoundShield product was granted the European Wound Closure Customer Value Leadership Award, Ultrasound Therapy – Wound Closure in 2014. WoundShield is intended to treat acute and chronic wounds with a disposable treatment patch that delivers localized therapeutic low frequency ultrasound. The WoundShield patch has two configurations: one that is placed adjacent to the wound and another, called the instillation patch, that is placed on the wound to enable instillation through sonophoresis, a process that increases the absorption of semisolid topical compounds, including medications, into the skin. Based on studies conducted by BIO-EC Microbiology Laboratory and Rosenblum, we believe that our WoundShield product possesses significant potential for the treatment of, among other things, diabetic foot ulcers and burns (Gasser P, Study Report delivered by BIO-EC Microbiology Laboratory, Dec 2007, which we ordered, paid for, and provided devices for; Rosenblum J, “Surface Acoustic Wave Patch Diathermy Generates Healing In Hard To Heal Wounds,” European Wound Management Association 2011, for which we supplied devices but had no further involvement).

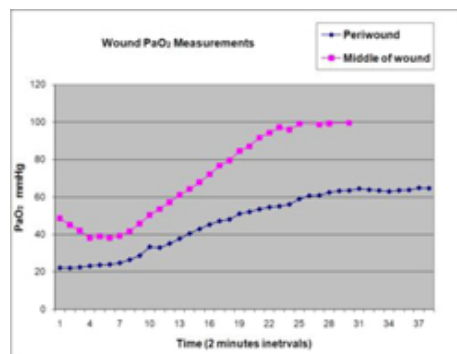


Picture of WoundShield Driver and Instillation Patch

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

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

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



In 2012, results were published of a human feasibility trial for the WoundShield instillation patch that was performed at Duke University in North Carolina. Seven patients were treated with the WoundShield instillation patch for their wounds and average tissue oxygen levels (PaO₂) increased by an average of 58% over baseline (Covington S, "Ultrasound-Mediated Oxygen Delivery to Lower Extremity Wounds," *Wounds* 2012; 24(8)). We supplied devices for this trial, but had no further involvement with it. Based upon the results of this trial, we are planning a series of clinical trials, which we expect to begin in the fourth quarter of 2017, with an end point claim that our WoundShield product enhances perfusion in chronic wounds.

Market for Wound-Healing Devices

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

Competition for WoundShield

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

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

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

We are also aware of a small clinical study, for which results were reported in August 2013, in which a small ultrasound device showed positive results in the treatment of venous ulcers, a type of chronic wound. Based upon currently available information about this device, we believe it will be at least 2018 before this device is available on the market for treatment of venous ulcers. We understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that of the transducer's diameter. We believe our products would have certain other advantages over this potential device, if developed, including that our products weigh less and are thinner. However, given the early stage of development of this potential device, we cannot say with certainty how our products would compare.

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

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

Regulatory Strategy

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

Our general regulatory strategy for WoundShield is focused on seeking U.S. Food and Drug Administration approval for a variety of indications. WoundShield obtained CE Mark approval in November 2012, and obtained Canadian License approval in November 2016, both for use in wound healing.

Sales and Marketing

WoundShield has generated minimal revenues to date. 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 United States is to find a strategic partner in the wound care market. We are actively pursuing this strategy. WoundShield could be an effective adjunct to existing wound treatment devices or a stand alone wound treatment modality.

Clinical Trials

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

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

Third Party Reimbursement

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

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

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

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

Obtaining reimbursement approval for a product from any government or other third party payer is a time-consuming and costly process that could require us or our distributors to provide supporting scientific, clinical and cost-effectiveness data for the use of our product to each payer. Even if a code is obtained for a product, a third party payer must still make coverage and payment determinations. When a payer determines that a product that is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities. We believe that the overall escalating costs of medical products and services has led to, and will continue to lead to, increased pressures on the health care industry to reduce the costs of products and services. In addition, recent health care reform measures, as well as legislative and regulatory initiatives at the federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third party payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

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

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

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

New Products Under Development

Renooskin

In 2016, we started developing a device for the facial rejuvenation market called Renooskin. Previous in vitro studies on human skin were done showing that the SAW technology provided skin rejuvenation comparable to Retinol A which is a well-accepted anti-aging cream. We have developed a head band like applicator for the PainShield SAW treatment and are in the process of arranging for a pilot trial with a cosmetic dermatologist and/or plastic surgeon. We believe that, subject to proof of efficacy of the Renooskin and receiving regulatory approval, the device can be sold in a non-reimbursement market since cosmetic devices are private pay. We expect the first articles to test in the third or fourth quarters of 2017.

Lungshield

A pilot study, adapting the UroShield technology to endotracheal tubes, is currently underway at Shaare Zedek Medical Center. The purpose of this study is to examine the effect of a device which generates low energy ultrasound waves like the UroShield product. The endpoint of the study is to show its effect on development of bacterial colonies on endotracheal tubes, in patient receiving mechanical ventilation, and to determine whether this effect lowers the rate of bacterial resistance to antibiotics. 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 have rights to six patents in the United States. Granted U.S. Patent No. 7,393,501 (having the following foreign counter-parts: China ZL03818327.7; Israel 165422; Japan 4504183; India 246351; Australia 2003231892; European Union 1511414 B), "Method, apparatus and system for treating biofilms associated with catheters" and granted U.S. Patent No. 7,829,029 (having the following foreign counter-parts: China ZL200780019732.3 and European Union 1998834), "Acoustic add-on device for biofilm prevention in urinary catheter," both relate to the use of surface acoustic waves to prevent biofilm formation on indwelling catheters. These granted U.S. patents expire on December 19, 2023 and October 27, 2025, respectively. Granted U.S. Patent No. 9,028,748, "System and method for surface acoustic wave treatment of medical devices," relate to methods of generating surface acoustic waves on medical device surfaces on both indwelling medical devices and implants to prevent biofilm formation. This U.S. patent expires on July 11, 2030. Granted U.S. Patent No. 9,585,977 (having the following foreign counter-parts: China ZL200780014875.5, European Union, and allowed Israel application), "System and method for surface acoustic waves treatment of skin," relates to methods of using surface acoustic waves for treatment of skin for the purpose of wound-healing, reducing infection, pain reduction and cosmetic enhancements. This U.S. patent expires August 20, 2033.

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

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

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

Trademarks

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

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). U.S. Patent No. 7,431,892 B2 has since expired. 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 United States. Before and after approval or clearance in the United States, our products, approved or cleared products and product candidates, are subject to extensive regulation by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. The U.S. Food and Drug Administration regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products. PainShield has already obtained 510(k) marketing approval by the U.S. Food and Drug Administration.

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

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

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

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

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

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

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

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

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

Clinical Trials of Medical Devices

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

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

Post-Approval Regulation of Medical Devices

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

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

Good Manufacturing Practices Requirements

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

International Regulation

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

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

The primary regulatory bodies and paths in Asia, Australia, 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, WoundShield and UroShield, a certificate by the Israel Ministry of Health allowing us to sell PainShield, WoundShield and UroShield in Israel, a certificate allowing us to sell PainShield in Australia, and we are able to sell PainShield, WoundShield and UroShield in India and Ecuador based on our CE Mark. In addition, our distributor in Korea has applied for approval to sell PainShield and UroShield. We generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

European Good Manufacturing Practices

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

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

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

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

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

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

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

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

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

Customers

We currently sell our products both through our website and distribution agreements, with approximately 25% of our sales coming through distributors in 2016. We have exclusive and non-exclusive distribution agreements for our products with medical product distributors based in the United States, various countries throughout Europe, India and Asia. We have recently enlisted Diligence Wound Care Global LLC on a solely incentive based basis, to assist in identifying and obtaining distribution in various parts of the world, in particular, Southeast Asia, China and Mexico.

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

Manufacturing and Suppliers

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

Employees

As of October 31, 2017, we had seven full-time employees and four contract employees. Two of the contract employees are sales related, one based in the United States, the other serving as United Kingdom Country Manager. 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.

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 expired on June 30, 2017, and we are in negotiations to renew the lease for another two years. The space is approximately 160 square meters. We pay approximately \$3,000 per month under our lease, which includes payments for electricity, cleaning services and taxes. 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.

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.

MANAGEMENT

Executive Officers and Directors

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.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Brian Murphy	60	Chief Executive Officer and Director
William Stern, Ph.D.	75	President
Stephen Brown	61	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 Ltd. 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. Mr. Murphy holds a bachelor of arts degree in communications from Southern Illinois University. Mr. Murphy's qualifications to serve on our board of directors include his significant sales, operations and general management experience in medical device and medical technology companies.

William Stern, Ph.D., President. Dr. Stern has served as our president since October 2016. Dr. Stern served as our vice chairman of the board of directors from October 2016 until October 2017 and, prior to that, as our chief executive officer and director since December 2014. 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 doctor of philosophy degree in engineering and physics from Columbia University and holds a master of science degree and a bachelor of science degree in electrical engineering from Columbia University and City College of New York, respectively.

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. In May 2017, Mr. Brown joined the board of directors of IDW Media Holdings, Inc. 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, 2014, and as our director since September 2003. From September 2003 to February 4, 2014, Dr. Jacob served as chairman of our board of directors and from September 2003 to March 1, 2014, Dr. Jacob served as our chief executive officer. Dr. Jacob also performed the functions of a principal financial officer until April 1, 2014. 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 us 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. 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, chief executive officer and president of KCI USA, the chairman of the board at Systagenix Ltd, the chairman of the board and chief executive officer of Spiracur Inc. and current chief executive officer of Atteris Healthcare LLC, a startup in San Antonio, Texas. He has a bachelor of arts degree from Upsala College and a master of business administration from Fairleigh Dickinson University. Mr. Fashek's extensive experience as an executive and leadership positions in the global medical device and pharmaceutical businesses, provide him the appropriate experience to serve on our board.

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 served 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 also serves as the Chairman of the Board of Directors of Ohr Pharmaceutical Inc. and 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 chief executive officer 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 and chief executive officer 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 United States, Europe and Japan over a period of 20 years, taking on the role of chief executive officer in several ventures. Earlier in his career, Mr. 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.

Our executive officers are party to certain agreements related to their service as such, described in “Executive Compensation – Agreements with Executive Officers.”

Family Relationships

There are no family relationships among any of our directors and executive officers.

Director Independence

Our board of directors has determined that Christopher Fashek, Michael Ferguson, Martin Goldstein, M.D., 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). Pursuant to NASDAQ rules, our board consists of a majority of independent directors.

The NASDAQ independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by NASDAQ rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director’s business and personal activities and relationships as they may relate to us and our management and did not rely on categorical standards other than those contained in the NASDAQ rule referenced above.

Board Committees

Pursuant to our amended and restated bylaws, our board of directors may establish committees of one or more directors from time-to-time, as it deems appropriate. Our common stock is quoted on the OTCQB under the symbol “NAOV.” The OTCQB does not maintain any standards requiring us to establish or maintain an audit, nominating or compensation committee. Effective as of the closing of this offering, our board of directors will establish an audit committee, a nominating and corporate governance committee and a compensation committee, each of which will have the composition and responsibilities described below. Each of these committees will operate under a written charter that will be approved by our board. Upon the closing of this offering, each committee charter will be posted on the corporate governance section of our website at www.nanovibronix.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus. Upon the consummation of this offering, each of the audit committee, a nominating and corporate governance committee and a compensation committee will have the composition and responsibilities described below.

Audit Committee. The audit committee will consist of Messrs. Thomas Mika (chair), Michael Ferguson and Christopher Fashek, each of whom our board has determined to be financially literate and qualify as an independent director under Sections 5605(a)(2) and 5605(c)(2) of the rules of the NASDAQ Stock Market and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended. In addition, Mr. Thomas Mika qualifies as an “audit committee financial expert,” as defined in Item 407(d)(5)(ii) of Regulation S-K. The function of the audit committee will be to assist the board of directors in its oversight of (1) the integrity of our financial statements, (2) our compliance with legal and regulatory requirements and (3) the qualifications, independence and performance of our independent auditors.

Nominating and Corporate Governance Committee. The nominating and corporate governance committee will consist of Messrs. Michael Ferguson (chair), Martin Goldstein and Christopher Fashek, each of whom our board has determined qualifies as an independent director under Section 5605(a)(2) of the rules of the NASDAQ Stock Market. The primary function of the nominating and corporate governance committee will be to identify individuals qualified to become board members, consistent with criteria approved by the board, and select the director nominees for election at each annual meeting of stockholders.

Compensation Committee. The compensation committee will consist of Messrs. Christopher Fashek (chair), Thomas Mika and Michael Ferguson, each of whom our board has determined qualifies as an independent director under Sections 5605(a)(2) and 5605(d)(2) of the rules of the NASDAQ Stock Market, as an “outside director” for purposes of Section 162(m) of the Internal Revenue Code and as a “non-employee director” for purposes of Section 16b-3 under the Securities Exchange Act of 1934, as amended. The function of the compensation committee will be to discharge the board of directors’ responsibilities relating to compensation of our directors and executives and our overall compensation programs. The primary objective of the compensation committee will be to develop and implement compensation policies and plans that are appropriate for us in light of all relevant circumstances and which provide incentives that further our long-term strategic plan and are consistent with our culture and the overall goal of enhancing enduring stockholder value.

Board Leadership Structure

The board of directors is committed to promoting our effective, independent governance. Our board believes it is in our best interests and the best interests of our stockholders for the board to have the flexibility to select the best director to serve as chairman at any given time, regardless of whether that director is an independent director or the chief executive officer. Consequently, we do not have a policy governing whether the roles of chairman of the board and chief executive officer should be separate or combined. This decision is made by our board of directors, based on our best interests considering the circumstances at the time.

Currently, the offices of the chairman of the board and the chief executive officer are held by two different people. Christopher Fashek is our independent, non-executive chairman of the board of directors, and Brian Murphy is our chief executive officer. The chief executive officer will be responsible for our day-to-day leadership and performance, while the chairman of the board of directors will provide guidance to the chief executive officer and set the agenda for board meetings and preside over meetings of the board. We believe that separation of the positions will reinforce the independence of the board in its oversight of our business and affairs, and create an environment that is more conducive to objective evaluation and oversight of management’s performance, increasing management accountability and improving the ability of the board to monitor whether management’s actions are in our best interests and those of our stockholders.

Role in Risk Oversight

Our board of directors oversees an enterprise-wide approach to risk management, designed to support the achievement of business objectives, including organizational and strategic objectives, to improve long-term organizational performance and enhance stockholder value. The involvement of our board of directors in setting our business strategy is a key part of its assessment of management’s plans for risk management and its determination of what constitutes an appropriate level of risk for the company. The participation of our board of directors in our risk oversight process includes receiving regular reports from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks.

While our board of directors has the ultimate responsibility for the risk management process, senior management and various committees of our board of directors will also have responsibility for certain areas of risk management.

Our senior management team is responsible for day-to-day risk management and regularly reports on risks to our full board of directors or a relevant committee. Our finance and regulatory personnel serve as the primary monitoring and evaluation function for company-wide policies and procedures, and manage the day-to-day oversight of the risk management strategy for our ongoing business. This oversight includes identifying, evaluating, and addressing potential risks that may exist at the enterprise, strategic, financial, operational, compliance and reporting levels.

The audit committee will focus on monitoring and discussing our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies. As appropriate, the audit committee will provide reports to and receive direction from the full board of directors regarding our risk management policies and guidelines, as well as the audit committee's risk oversight activities.

In addition, the compensation committee will assess our compensation policies to confirm that the compensation policies and practices do not encourage unnecessary risk taking. The compensation committee will review and discuss the relationship between risk management policies and practices, corporate strategy and senior executive compensation and, when appropriate, report on the findings from the discussions to our board of directors. Our compensation committee intends to set performance metrics that will create incentives for our senior executives that encourage an appropriate level of risk-taking that is commensurate with our short-term and long-term strategies.

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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the Securities and Exchange Commission on March 31, 2017. We intend to disclose future amendments to certain provisions of the code of ethics, or waivers of such provisions granted to executive officers and directors, on our website at www.nanovibronix.com within four business days following the date of such amendment or waiver.

EXECUTIVE COMPENSATION

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 annual compensation in 2016 or 2015 that exceeded \$100,000.

Name and Principal Position	Year	Salary (\$)(1)	Bonus (\$)	Option Awards (\$)(2)	All Other Compensation (\$)(1)	Total (\$)(1)
Harold Jacob, M.D. Former Chief Executive Officer and Former Chairman of the Board of Directors	2016	-	-	-	10,763(3)	10,763
	2015	-	-	-	10,809(3)	10,809
Brian Murphy Chief Executive Officer	2016	31,690(4)	-(4)	21,250	-	52,940
	2015	-	-	-	-	-
William Stern, Ph.D. President, former Chief Executive Officer and former Vice-Chairman/ Director	2016	48,000(5)	10,600	117,311	-	175,911
	2015	36,000(5)	14,000	66,711	-	116,711
Stephen Brown Chief Financial Officer	2016	90,000	28,000	31,624	-	149,624
	2015	50,000	-	22,237	-	72,237
Jona Zumeris, Ph.D. Vice President of Technology and Director	2016	111,128	-	31,624	42,033(6)	184,785
	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 ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the market price 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.
- (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 Industries, Inc. (“Multigon”) for use of 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.

Agreements with Executive Officers

Brian Murphy

On October 13, 2016, we entered into an employment agreement with Mr. Murphy, effective as of the same date. The term of Mr. Murphy’s employment as the chief executive officer of the Company is 3 years unless earlier 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. 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.

Under this employment agreement, we shall pay Mr. Murphy an annual salary of \$181,000 less applicable payroll deductions and tax withholdings for all services rendered by him under the employment 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. We 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 of directors which was approved in full in 2016. For 2018 and all subsequent years of Mr. Murphy’s employment, Mr. Murphy 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.

Either party may terminate the agreement for any reason, provided that Mr. Murphy is required to provide 90 days prior written notice to us. In addition, we may terminate Mr. Murphy’s employment for “cause,” after a 30 day cure period, if the circumstances are curable. If we terminate Mr. Murphy’s employment without cause, or if Mr. Murphy resigns for “good reason” after a 30 day cure period, Mr. Murphy is entitled to (A) any unpaid base salary accrued through the termination date, any accrued and unpaid vacation pay and any unreimbursed expenses properly incurred prior to the termination date; (B) a severance pay equal to Mr. Murphy’s base salary for 12 months plus the target performance bonus for the year in which the termination date occurs; (C) any earned but unpaid performance bonus relating to the calendar year prior to the calendar year in which the termination date occurs; and (D) an additional lump sum cash payment sufficient to provide Mr. Murphy the equivalent of our portion of the premium under the health insurance benefits for the 12 months of Consolidated Omnibus Budget Reconciliation Act coverage. Mr. Murphy has no specific right to terminate the employment agreement as a result of a change in control (as defined in the employment agreement); however, if following a change in control, during the term of Mr. Murphy’s employment, either Mr. Murphy terminates his employment with us for good reason, or we terminate Mr. Murphy without cause, all stock options, restricted stock, stock appreciation rights or similar stock-based rights granted to Mr. Murphy shall vest in full and become immediately exercisable.

In addition, Mr. Murphy is eligible to receive certain stock options, restricted stock, stock appreciation rights or similar stock-based rights granted to Mr. Murphy as set forth separately in applicable award agreements.

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.

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 was 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.

On June 16, 2014, 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. The first amendment to Dr. Zumeris’s employment agreement also contains certain noncompetition, non-solicitation, non-disparagement, confidentiality and assignment of work product requirements for Dr. Zumeris.

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.

William Stern, Ph.D.

Dr. Stern served as our chief executive officer from December 2014 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.

Under this employment agreement, Dr. Stern was previously 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. As of October 11, 2017, Dr. Stern is no longer entitled to such fee.

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

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.

Name	Date of Grant	Option Awards		Option Exercise Price (\$)	Option Expiration Date
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
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:

<u>Name</u>	<u>Fees earned or paid in cash (\$)</u>	<u>Stock awards (\$)</u>	<u>Option awards (\$)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>Nonqualified Deferred Compensation Earnings (\$)</u>	<u>All other Compensation (\$)</u>	<u>Total (\$)</u>
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 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 July 16, 2016 we approved the following compensation package for independent directors: (i) an additional annual grant of options to purchase 20,000 shares of common stock to the chairman of the board of directors; and (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.

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, 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, 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.

Equity Compensation Plan Information

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:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) 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	\$ 3.27	-
Equity compensation plans not approved by security holders	332,181(1)	4.83	-
Total	1,294,577	\$ 3.67	-

(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.

Directors' and Officers' Liability Insurance

We currently have directors' and officers' liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures us against losses which we may incur in indemnifying our officers and directors. In addition, such persons also have indemnification rights under applicable laws, and our certificate of incorporation and bylaws.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Generally, we do not 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, 2014, April 1, 2014, May 15, 2014, June 16, 2014, August 7, 2014, September 7, 2014, October 13, 2014, November 19, 2014 and December 11, 2014, we issued secured convertible promissory notes to two funds controlled by Paul Packer. Mr. Packer served as our director from January 2005 until his resignation on January 15, 2014, and is a beneficial owner of more than 5% of our common stock. 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, 2014, 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, 2014, April 1, 2014, May 15, 2014, June 16, 2014, August 7, 2014, September 7, 2014, October 13, 2014, November 19, 2014 and December 11, 2014, 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, 2014, 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 was to be terminated 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, 2014, pursuant to a restricted stock award agreement, fully vesting 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 were subject to forfeiture until vested and would have been 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. Although the agreement has not been formally terminated, AYTA Consulting, LLC does not currently provide any services to us and we do not pay any compensation to AYTA Consulting, LLC under this agreement.

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 (such warrants, the "Two-Year Warrants"). Pursuant to these agreements, we issued 666,667 shares of Series C Preferred Stock, Two-Year Warrants to purchase 266,667 shares of common stock at an exercise price of \$3.00 per share and Two-Year 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 beneficial owner of more than 5% of our common stock, and 166,667 shares of Series C Preferred Stock, Two-Year Warrants to purchase 66,666 shares of common stock at an exercise price of \$3.00 per share and Two-Year Warrants to purchase 66,666 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. (the “Services Agreement”). 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 October 11, 2017, we increased the monthly fee under the Services Agreement to \$7,000 per month.

On March 25, 2015, we issued warrants to purchase up to 61,000 shares of common stock to AYTA Consulting, LLC, an entity controlled by Mr. Packer, 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 \$2.57 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. See “Description of Securities—Warrants—March 2015 Warrants.”

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 the Two-Year Warrants to extend the expiration date of the Two-Year Warrants for two additional years. Pursuant to the warrant amendment, the Two-Year Warrants to purchase 266,667 shares of common stock at \$3.00 per share and the Two-Year Warrants to purchase 266,667 shares of common stock at \$6.00 per share will expire on January 29, 2019, and the Two-Year Warrants to purchase 140,000 shares of common stock at \$3.00 per share and the Two-Year Warrants to purchase 140,000 shares of common stock at \$6.00 per share will expire on February 10, 2019, and the Two-Year Warrants to purchase 13,333 shares of common stock at \$3.00 per share and the Two-Year 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 Two-Year Warrants remain the same. Holders of the Two-Year Warrants who entered into the warrant amendment with us include (i) a subsidiary of IDT Corporation, a beneficial owner of more than 5% of our common stock, who holds Two-Year Warrants to purchase 266,667 shares of common stock at \$3.00 per share and Two-Year 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 Two-Year Warrants to purchase 66,666 shares of common stock at \$3.00 per share and Two-Year 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 we received from Mr. Packer and entities controlled by Mr. Packer \$250,000 of loans and issued to Mr. Packer and entities controlled by Mr. Packer 2017 Notes in an aggregate principal amount of \$250,000 and 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Events,” “Description of Securities—Warrants—2017 Warrants” and “Recent Sales of Unregistered Securities” for more information on the terms of the 2017 Notes and the 2017 Warrants.

On May 3, 2017, we completed a bridge financing, pursuant to which we received from Mr. Packer \$30,000 of loans and issued to Mr. Packer 2017 Notes in an aggregate principal amount of \$30,000 and 2017 Warrants to purchase an aggregate of 12,000 shares of common stock at an initial exercise price of \$5.90 per share, subject to adjustment, and are immediately exercisable. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Events,” “Description of Securities—Warrants—2017 Warrants” and “Recent Sales of Unregistered Securities” for more information on the terms of the 2017 Notes and the 2017 Warrants.

On June 3, 2017, we completed a bridge financing, pursuant to which we received from an entity controlled by Mr. Packer \$500,000 of loans and issued to an entity controlled by Mr. Packer 2017 Notes in an aggregate principal amount of \$500,000 and 2017 Warrants to purchase an aggregate of 200,000 shares of common stock at an initial exercise price of \$5.90 per share, subject to adjustment, and are immediately exercisable. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Events,” “Description of Securities—Warrants—2017 Warrants” and “Recent Sales of Unregistered Securities” for more information on the terms of the 2017 Notes and the 2017 Warrants.

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 October 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.

Certain of our affiliates have indicated an interest in participating in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these affiliates may determine to purchase fewer securities than they have indicated an interest in purchasing or not to purchase any securities in this offering. The following table does not reflect any potential purchases by these affiliates.

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, Neshet, Israel 36651. As of October 31, 2017, we had 2,632,710 shares of common stock and 2,310,256 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 Before Offering(1)	Percentage Beneficially Owned After Offering
5% Owners			
Rennova Health, Inc. (f.k.a. CollabRx, Inc.) (2)	205,095	7.8%	4.8%
IDT Corporation(3)	273,950(4)	9.9%	9.9%
Paul Packer(5)	273,967(6)	9.9%	9.9%
Miriam Winder-Kelly(7)	262,485(8)	9.8%	6.1%
Orin Hirschman(9)	240,320(10)	9.1%	9.9%
Officers and Directors			
William Stern, Ph.D.	157,000(11)	5.6%	3.6%
Stephen Brown	40,667(12)	1.5%	1.0%
Harold Jacob, M.D.	225,773(13)	8.2%	5.2%
Jona Zumeris, Ph.D.	220,975(14)	7.9%	5.0%
Martin Goldstein, M.D.	81,000(15)	2.9%	1.9%
Michael Ferguson	40,000(16)	1.5%	1.0%
Thomas R. Mika	40,000(17)	1.5%	1.0%
Christopher Fashek	22,920(18)	*	*
Brian Murphy	45,840	1.7%	1.1%
All directors and executive officers as a group (9 persons)	874,174	31.5%	17.7%

* 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 September 11, 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) 70,239 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) 107,780 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) 917,590 shares of common stock issuable upon conversion of Series C Preferred Stock held by Globis Capital Partners, L.P., (ii) 298,919 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) 162,073 shares of common stock that may be purchased by Globis Capital Partners, L.P. upon the exercise of warrants, and 31,927 shares of common stock that can be purchased by conversion of a note payable (ii) 60,955 shares of common stock that may be purchased by Globis Overseas Fund, Ltd. upon the exercise of warrants and 11,707 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) 95,672 shares of common stock that may be purchased by Mr. Packer upon the exercise of warrant and 15,871 shares of common stock that can be purchased by conversion of note payable (iv) 200,000 shares of common stock that may be purchased by Globis Asia, L.P. upon the exercise of warrants, and 104,271 shares of common stock that can be purchased by conversion of a 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, and Globis Asia LP. Mr. Packer is deemed to have beneficial ownership of the shares held by Globis Capital Partners, L.P., Globis Overseas Fund, Ltd., Globis Asis LP. 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 157,000 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.
- (18) Comprised of 22,920 shares of common stock that may be purchased by Mr. Fashek upon exercise of stock options that are exercisable within 60 days.

MATERIAL U.S. FEDERAL TAX CONSEQUENCES

The following is a general summary of material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our warrants and shares of our common stock or Preferred Stock in the offering and the acquisition, ownership, and disposition of our shares of common stock issuable upon conversion of the Preferred Stock or upon the exercise of our warrants.

Scope of this Summary

This summary is for general information purposes only and does not purport to be a complete analysis of all potential U.S. federal income tax consequences of the acquisition, ownership and disposition of our warrants, common stock and Preferred Stock. Except as specifically set forth below, this summary does not discuss applicable tax reporting requirements. In addition, this summary does not take into account the individual facts and circumstances of any particular holder that may affect the U.S. federal income tax consequences to such holder. Accordingly, this summary is not intended to be, and should not be construed as, legal or U.S. federal income tax advice with respect to any particular holder. Each holder should consult its own tax advisors regarding the U.S. federal, state and local, and non-U.S. tax consequences of the acquisition, ownership and disposition of our warrants, common stock and Preferred Stock.

No legal opinion from U.S. legal counsel or ruling from the Internal Revenue Service (the "IRS") has been requested, or will be obtained, regarding the U.S. federal income tax consequences of the acquisition, ownership and disposition of our warrants, common stock and Preferred Stock. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary.

Authorities

This summary is based on the Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations, published rulings of the IRS, published administrative positions of the IRS, and U.S. court decisions that are applicable and, in each case, as in effect and available, as of the date of this prospectus. Any of the authorities on which this summary is based could be changed in a material and adverse manner at any time, and any such change could be applied on a retroactive basis.

U.S. Holders

As used in this summary, the term "U.S. Holder" means a beneficial owner of (i) our warrants, common stock or Preferred Stock acquired pursuant to this prospectus or (ii) our common stock acquired upon conversion of the Preferred Stock or exercise of our warrants that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S.;

- a corporation (or other entity taxable as a corporation) organized under the laws of the U.S., any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States. and the control of one or more U.S. persons for all substantial decisions or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Non-U.S. Holders

The term “Non-U.S. Holder” means any beneficial owner of (i) our warrants, common stock or Preferred Stock acquired pursuant to this prospectus or (ii) our common stock acquired upon conversion of the Preferred Stock or upon the exercise of our warrants that is not a U.S. Holder.

Holders Subject to Special U.S. Federal Income Tax Rules

This summary deals only with persons or entities who (i) acquire our warrants, common stock or Preferred Stock in the offering or (ii) who receive our common stock upon the conversion of the Preferred Stock or upon the exercise of our warrants, and who hold such stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment purposes). This summary does not address all aspects of U.S. federal income taxation that may be applicable to holders in light of their particular circumstances or to holders subject to special treatment under U.S. federal income tax law, such as (without limitation): banks, insurance companies, and other financial institutions; dealers or traders in securities, commodities or foreign currencies; regulated investment companies; U.S. expatriates or former long-term residents of the U.S.; persons holding our warrants, common stock or Preferred Stock as part of a straddle, appreciated financial position, synthetic security, hedge, conversion transaction or other integrated investment; persons holding our warrants, common stock or Preferred Stock as a result of a constructive sale; entities that acquire our warrants, common stock or Preferred Stock that are treated as partnerships for U.S. federal income tax purposes and partners in such partnerships; real estate investment trusts; U.S. Holders that have a “functional currency” other than the U.S. dollar; holders that acquired our warrants, common stock or Preferred Stock in connection with the exercise of employee stock options or otherwise as consideration for services; or holders that are “controlled foreign corporations” or “passive foreign investment companies.” Holders that are subject to special provisions under the Code, including holders described immediately above, should consult their own tax advisors regarding the U.S. federal, state and local, and non-U.S. tax consequences arising from and relating to the acquisition, ownership and disposition of our warrants, common stock and Preferred Stock.

If an entity or arrangement that is classified as a partnership (or other “pass-through” entity) for U.S. federal income tax purposes holds our warrants, common stock or Preferred Stock, the U.S. federal income tax consequences to such entity and the partners (or other owners) of such entity generally will depend on the activities of the entity and the status of such partners (or owners). This summary does not address the tax consequences to any such owner or entity. Partners (or other owners) of entities or arrangements that are classified as partnerships or as “pass-through” entities for U.S. federal income tax purposes should consult their own tax advisors regarding the U.S. federal income tax consequences arising from and relating to the acquisition, ownership, and disposition of our warrants, common stock and Preferred Stock.

Tax Consequences Not Addressed

This summary does not address the U.S. state and local, U.S. federal estate and gift, U.S. federal alternative minimum tax, or non-U.S. tax consequences to holders of the acquisition, ownership, and disposition of our warrants, common stock or Preferred Stock. Each holder should consult its own tax advisors regarding the U.S. state and local, U.S. federal estate and gift, U.S. federal alternative minimum tax, and non-U.S. tax consequences of the acquisition, ownership, and disposition of our warrants, common stock and Preferred Stock.

U.S. Federal Income Tax Consequences to U.S. Holders of the Acquisition, Ownership and Disposition of Our Warrants, Common Stock and Preferred Stock

Distributions

Distributions made on our common stock and Preferred Stock generally will be included in a U.S. Holder's income as ordinary dividend income to the extent of our current and accumulated earnings and profits (determined under U.S. federal income tax principles) as of the end of our taxable year in which the distribution occurs. Dividends received by non-corporate U.S. Holders are generally taxed at a maximum tax rate of 20%, provided certain holding period and other requirements are satisfied. Distributions in excess of our current and accumulated earnings and profits will be treated as a return of capital to the extent of a U.S. Holder's adjusted tax basis in our common stock and Preferred Stock and thereafter as capital gain from the sale or exchange of such stock, which will be taxable according to rules discussed under the heading "Sale, Certain Redemptions or Other Taxable Dispositions of our warrants, common stock and Preferred Stock," below. Dividends received by a corporate holder may be eligible for a dividends received deduction, subject to applicable limitations.

Sale, Certain Redemptions or Other Taxable Dispositions of Our Warrants, Common Stock and Preferred Stock

Upon the sale, redemption, or other taxable disposition of our warrants, common stock or Preferred Stock, a U.S. Holder generally will recognize capital gain or loss equal to the difference between (i) the amount of cash and the fair market value of any property received upon such taxable disposition and (ii) the U.S. Holder's adjusted tax basis in the warrants or shares, as applicable. Such capital gain or loss will be long-term capital gain or loss if a U.S. Holder's holding period in our warrants, common stock or Preferred Stock is more than one year at the time of the taxable disposition. Long-term capital gains recognized by non-corporate U.S. Holders will generally be subject to a maximum U.S. federal income tax rate of 20%. Deductions for capital losses are subject to limitations.

Conversion of Preferred Stock Into Common Stock

A U.S. Holder will not recognize any gain or loss by reason of receiving our common stock upon conversion of the Preferred Stock, except that the fair market value of any shares of our common shares attributable to dividend arrearages generally will be treated as a constructive distribution, and will be taxable, as described above under "—Distributions." A U.S. Holder's initial tax basis in our common stock received upon the conversion of its Preferred Stock should be equal to such U.S. Holder's tax basis in its converted Preferred Stock, other than common stock attributable to dividend arrearages. A U.S. Holder's holding period for the common stock received upon the conversion of its Preferred Stock should carry over from the converted Preferred Stock, other than common stock attributable to dividend arrearages.

Exercise of Warrants

A U.S. Holder generally will not recognize gain or loss on the exercise of our warrants and related receipt of our common stock (unless cash is received in lieu of the issuance of a fractional share of our common stock). A U.S. Holder's initial tax basis in our common stock received on the exercise of a warrant should be equal to the sum of (a) such U.S. Holder's tax basis in such warrant plus (b) the exercise price paid by such U.S. Holder on the exercise of such warrant. A U.S. Holder's holding period for our common stock received on the exercise of a warrant should begin on the date that such warrant is exercised by such U.S. Holder.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of shares of our common stock that will be issued on the exercise of the warrants, or an adjustment to the exercise price of our warrants, may be treated as a constructive distribution to a U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of a warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of our warrants should generally not result in a constructive distribution.

Other U.S. Federal Income Tax Consequences Applicable to U.S. Holders

Additional Tax on Passive Income

Individuals, estates and certain trusts whose income exceeds certain thresholds will be required to pay a 3.8% Medicare surtax on "net investment income" including, among other things, dividends on and net gain from the disposition of our warrants, common stock or Preferred Stock. U.S. Holders should consult their own tax advisors regarding the effect, if any, of this tax on their ownership and disposition of our warrants, common stock or Preferred Stock.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends on our common stock or Preferred Stock and to the proceeds of a sale of our warrants, common stock or Preferred Stock paid to a U.S. Holder unless the U.S. Holder is an exempt recipient (such as a corporation). Backup withholding will apply to those payments if the U.S. Holder fails to provide its correct taxpayer identification number, or certification of exempt status, or if the U.S. Holder is notified by the IRS that it has failed to report in full payments of interest and dividend income. Backup withholding is not an additional tax, and any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability, if any, provided the required information is furnished in a timely manner to the IRS.

U.S. Federal Income Tax Consequences to Non-U.S. Holders of the Acquisition, Ownership and Disposition of Our Warrants, Common Stock and Preferred Stock

Conversion of Preferred Stock Into Common Stock

A Non-U.S. Holder will not recognize any gain or loss by reason of receiving our common stock upon conversion of the Preferred Stock, except that the fair market value of any shares of our common stock attributable to dividend arrearages generally will be treated as a constructive distribution, and will be taxable, as described below under “U.S. Federal Income Tax Consequences to Non-U.S. Holders of the Acquisition, Ownership and Disposition of Our Warrants, Common Stock and Preferred Stock —Distributions.” A Non-U.S. Holder’s initial tax basis in the common shares received upon the conversion of its Preferred Stock should be equal to such Non-U.S. Holder’s tax basis in its converted Preferred Stock, other than common stock attributable to dividend arrearages. A Non-U.S. Holder’s holding period for the common stock received upon the conversion of its Preferred Stock should carry over from the converted Preferred Stock, other than common stock attributable to dividend arrearages.

Exercise of Warrants

A Non-U.S. Holder generally will not recognize gain or loss on the exercise of a warrant and related receipt of our common stock (unless cash is received in lieu of the issuance of a fractional share of common stock and certain other conditions are present, as discussed below under “Sale or Other Taxable Disposition of Our Warrants, Common Stock and Preferred Stock”). A Non-U.S. Holder’s initial tax basis in our common stock received on the exercise of a warrant should be equal to the sum of (a) such Non-U.S. Holder’s tax basis in such warrant plus (b) the exercise price paid by such Non-U.S. Holder on the exercise of such warrant. A Non-U.S. Holder’s holding period for our common stock received on the exercise of a warrant should begin on the date that such warrant is exercised by such Non-U.S. Holder.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of our common stock that will be issued on the exercise of our warrants, or an adjustment to the exercise price of our warrants, may be treated as a constructive distribution to a Non-U.S. Holder of our warrants if, and to the extent that, such adjustment has the effect of increasing such Non-U.S. Holder’s proportionate interest in our “earnings and profits” or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders).

Distributions

Distributions on our common stock or Preferred Stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital and will first reduce a Non-U.S. Holder’s basis in our common shares or Preferred Stock, but not below zero, and then will be treated as gain from the sale of stock, which will be taxable according to rules discussed under the heading “Sale or Other Taxable Disposition of Our Warrants, Common Stock And Preferred Stock,” below. Any dividends paid to a Non-U.S. Holder with respect to our common shares or Preferred Stock generally will be subject to withholding tax at a 30% gross rate, subject to any exemption or lower rate under an applicable treaty if the Non-U.S. Holder provides us with a properly executed IRS Form W-8BEN-E or W-8BEN. A Non-U.S. Holder that provides us with a properly executed IRS Form W-8ECI (or other applicable form) relating to income effectively connected with the conduct of a trade or business within the United States will not be subject to the 30% withholding tax.

Dividends that are effectively connected with the conduct of a trade or business within the United States are not subject to the withholding tax (assuming proper certification and disclosure), but instead are subject to U.S. federal income tax on a net income basis at applicable graduated individual or corporate rates, subject to an applicable treaty that provides otherwise. Any such effectively connected income received by a non-U.S. corporation may, under certain circumstances, be subject to an additional branch profits tax on its effectively connected earnings and profits at a 30% rate, subject to any exemption or lower rate as may be specified by an applicable income tax treaty.

A Non-U.S. Holder of our common shares or Preferred Stock who wishes to claim the benefit of an applicable treaty rate or exemption is required to satisfy certain certification and other requirements. If a Non-U.S. Holder is eligible for an exemption from or a reduced rate of U.S. withholding tax pursuant to an income tax treaty, it may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Sale or Other Taxable Disposition of Our Warrants, Common Stock and Preferred Stock

In general, a Non-U.S. Holder of our warrants, common stock or Preferred Stock will not be subject to U.S. federal income tax on gain recognized from a sale, exchange, or other taxable disposition of such warrants or stock, unless:

- the gain is effectively connected with a U.S. trade or business carried on by the Non-U.S. Holder (and, where an income tax treaty applies, is attributable to a U.S. permanent establishment of the Non-U.S. Holder), in which case the Non-U.S. Holder will be subject to tax on the net gain from the sale at regular graduated U.S. federal income tax rates, and if the Non-U.S. Holder is a corporation, may be subject to an additional U.S. branch profits tax at a gross rate equal to 30% of its effectively connected earnings and profits for that taxable year, subject to any exemption or lower rate as may be specified by an applicable income tax treaty;

- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met, in which case the Non-U.S. Holder will be subject to a 30% tax on the gain from the sale, which may be offset by U.S. source capital losses; or
- we are or have been a “United States real property holding corporation” (“USRPHC”) for U.S. federal income tax purposes at any time during the shorter of the Non-U.S. Holder’s holding period or the 5-year period ending on the date of disposition of our warrants, common shares or Preferred Stock; provided, with respect to our warrants, common stock and Preferred Stock, that as long as our common stock is regularly traded on an established securities market as determined under the Treasury Regulations (the “Regularly Traded Exception”), a Non-U.S. Holder would not be subject to taxation on the gain on the sale of our warrants, common shares or Preferred Stock under this rule unless the Non-U.S. Holder has owned more than 5% of our common stock at any time during such 5-year or shorter period (a “5% Shareholder”). In addition, certain attribution rules apply in determining ownership for this purpose. While the common stock will be listed on the OTCQB and therefore may satisfy the Regularly Traded Exception, since our warrants and the Preferred Stock are not expected to be listed on a securities market, our warrants and the Preferred Stock are unlikely to qualify for the Regularly Traded Exception. Non-U.S. Holders should be aware that we have made no determination as to whether we are or have been a USRPHC, and we can provide no assurances that we are not and will not become a USRPHC in the future. In addition, in the event that we are or become a USRPHC, we can provide no assurances that our common stock will meet the Regularly Traded Exception at the time a Non-U.S. Holder purchases such securities or sells, exchanges or otherwise disposes of such securities. Non-U.S. Holders should consult with their own tax advisors regarding the consequences to them of investing in a USRPHC. As a USRPHC, a Non-U.S. Holder will be taxed as if any gain or loss were effectively connected with the conduct of a trade or business as described above in “Dividends” in the event that (i) such holder is a 5% Shareholder, or (ii) the Regularly Traded Exception is not satisfied during the relevant period.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS and to Non-U.S. Holders the amount of dividends paid on our common stock and Preferred Stock to Non-U.S. Holders and the amount of tax, if any, withheld with respect to those payments. Copies of the information returns reporting such dividends and withholding may also be made available to the tax authorities in the country in which a Non-U.S. Holder resides under the provisions of an applicable income tax treaty.

In general, a Non-U.S. Holder will not be subject to backup withholding with respect to payments of dividends that we make, provided we receive a statement meeting certain requirements to the effect that the Non-U.S. Holder is not a U.S. person and we do not have actual knowledge or reason to know that the holder is a U.S. person, as defined under the Code, that is not an exempt recipient. The requirements for the statement will be met if (1) the Non-U.S. Holder provides its name, address and U.S. taxpayer identification number, if any, and certifies, under penalty of perjury, that it is not a U.S. person (which certification may be made on IRS Form W-8BEN or W-8BEN-E, as applicable) or (2) a financial institution holding the instrument on behalf of the Non-U.S. Holder certifies, under penalty of perjury, that such statement has been received by it and furnishes us or our paying agent with a copy of the statement. In addition, a Non-U.S. Holder will be subject to information reporting and, depending on the circumstances, backup withholding with respect to payments of the proceeds of a sale of our warrants, common stock or Preferred Stock within the United States or conducted through certain U.S.-related financial intermediaries, unless the statement described above has been received, and we do not have actual knowledge or reason to know that a holder is a U.S. person, as defined under the Code, that is not an exempt recipient, or the Non-U.S. Holder otherwise establishes an exemption. Backup withholding is not an additional tax and any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a Non-U.S. Holder’s U.S. federal income tax liability, if any, provided the required information is furnished in a timely manner to the IRS.

Rules Relating to Foreign Accounts

Generally, we will be required to withhold tax at a rate of 30% on dividends in respect of our common stock and Preferred Stock, and gross proceeds from the sale of our common stock and Preferred Stock held by or through certain foreign entities, in the case of dividends, and beginning after December 31, 2018, in the case of such gross proceeds, unless such entity is in compliance with its obligations under the Foreign Account Tax Compliance Act, or “FATCA.”

DESCRIPTION OF SECURITIES

We have authorized 25,000,000 shares of capital stock, par value \$0.001 per share, of which 20,000,000 are shares of common stock and 5,000,000 are shares of “blank check” preferred stock. On October 31, 2017, there were 2,632,710 shares of common stock and 2,310,256 shares of Series C Preferred Stock issued and outstanding, and no shares of Preferred Stock issued and outstanding. We currently have 3,000,000 shares of preferred stock designated as Series C Preferred Stock and will have 647 shares of preferred stock designated as Series D Preferred Stock. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors does not intend to seek stockholder approval for the issuance and sale of our common stock or preferred stock.

Common Stock

The holders of common stock are entitled to one vote per share. Our certificate of incorporation does not provide for cumulative voting. All of our directors hold office for one-year terms until the election and qualification of their successors. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by the board of directors out of legally available funds. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of the board of directors and issued in the future.

The transfer agent and registrar for our common stock is VStock Transfer, LLC. The transfer agent’s address is 18 Lafayette Place, Woodmere, New York 11598. Our common stock is currently listed on the OTCQB under the symbol “NAOV,” and has been approved for listing on The NASDAQ Capital Market under the symbol “NAOV.”

Preferred Stock

The board of directors is authorized, subject to any limitations prescribed by law, without further vote or action by the stockholders, to issue from time to time shares of preferred stock in one or more series. Each such series of preferred stock shall have such number of shares, designations, preferences, voting powers, qualifications, and special or relative rights or privileges as shall be determined by the board of directors, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights. Issuance of preferred stock by our board of directors may result in such shares having dividend and/or liquidation preferences senior to the rights of the holders of our common stock and could dilute the voting rights of the holders of our common stock.

Prior to the issuance of shares of each series of preferred stock, the board of directors is required by the Delaware General Corporation Law and our certificate of incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- the number of shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of shares then outstanding) from time to time by action of the board of directors;
- the dividend rate and the manner and frequency of payment of dividends on the shares of that series, whether dividends will be cumulative, and, if so, from which date;

- whether that series will have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights;
- whether that series will have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors may determine;
- whether or not the shares of that series will be redeemable, and, if so, the terms and conditions of such redemption;
- whether that series will have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;
- whether or not the shares of the series will have priority over or be on a parity with or be junior to the shares of any other series or class in any respect;
- the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of shares of that series; and
- any other relative rights, preferences and limitations of that series.

Once designated by our board of directors, each series of preferred stock may have specific financial and other terms.

Series C Convertible Preferred Stock

On October 31, 2017, there were 2,310,256 shares of Series C Preferred Stock issued and outstanding, held by 6 stockholders.

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 beneficially 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 us.

In the event of liquidation, dissolution, or winding up, whether voluntarily or involuntarily, each holder of Series C Preferred Stock could elect to receive 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 for such purposes to the 9.99% beneficial ownership limitation), subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Series C Preferred Stock as to distributions of assets upon such event.

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. We are 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 9.99% beneficial ownership limitations) with respect to any and all matters presented to the stockholders for their action or consideration. Holders of Series C Preferred Stock vote together with the holders of common stock as a single class, except as provided by law and except that the consent of holders of a majority of the outstanding Series C Preferred Stock is required to amend the terms of the Series C Preferred Stock.

Series D Convertible Preferred Stock Being Issued in this Offering

The following summary of certain terms and provisions of the Preferred Stock offered in this offering is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in our certificate of designation of preferences, rights and limitations of the Preferred Stock, which has been filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the certificate of designation of the Preferred Stock for a complete description of the terms and conditions of the Preferred Stock.

Conversion. Each share of Preferred Stock is convertible at any time at the holder's option into 1,000 shares of common stock (subject to the beneficial ownership limitations as provided in the related certificate of designation of preferences), subject to adjustment as provided in the certificate of designation, provided that the holder will be prohibited from converting 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 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until the 61st day after such notice to us.

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

Dividend Rights. Shares of Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Preferred Stock are entitled to receive dividends on shares of 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 our board of directors, except for stock dividends or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents for which the conversion price will be adjusted. We are not obligated to redeem or repurchase any shares of Preferred Stock. Shares of Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

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

Failure to Deliver Conversion Shares. If we fail to timely deliver shares of common stock upon conversion of the Preferred Stock (the "Conversion Shares"), within the time period specified in the certificate of designation (within three trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), and if the holder has not exercised its Buy-In rights as described below with respect to such shares, then we are obligated to pay to the holder, as liquidated damages, an amount equal to \$50 per business day (increasing to \$100 per trading day after the third trading day and to \$200 per trading day after the sixth trading day after such damages begin to accrue) for each trading day following the required delivery date for the Conversion Shares for timely delivery under the certificate of designation, for each \$5,000 of the stated value of the Preferred Stock being converted which are not timely delivered.

Compensation for Buy-In on Failure to Timely Deliver Shares. If we fail to timely deliver the Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise), or the holder's brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the Conversion Shares which the holder anticipated receiving upon such conversion (a "Buy-In"), then we are obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased exceeds (y) the amount obtained by multiplying (1) the aggregate number of shares of common stock the holder was entitled to receive from the conversion at issue and (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions), and (B) at the option of the holder, either reinstate the portion of the Preferred Stock equal to the number of shares of Preferred Stock submitted for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had we timely complied with its conversion and delivery obligations.

Fundamental Transaction. If, at any time while the Preferred Stock is outstanding, (i) we, in one or more related transactions effects any merger or consolidation of us with or into another person, (ii) we effect any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) we complete any tender offer or exchange offer (whether by us or another person) pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property, or (iv) we effect any reclassification of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property (each a "Fundamental Transaction"), then upon any subsequent conversion of the Preferred Stock, the holder will receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the number of shares of common stock of the successor or acquiring corporation or of the Corporation, if it is the surviving corporation, and any additional cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction (without regard to the beneficial ownership limitation) (the "Alternate Consideration"). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction. If a Fundamental Transaction is also a change of control transaction (acquisition by an individual or legal entity or "group" of effective control of in excess of 50% of our voting securities, a merger or consolidation between us and any other person that, after giving effect to such transaction, our stockholders immediately prior to such transaction own less than 50% of the aggregate voting power of us or the successor entity of such transaction, or our disposal of all or substantially all of our assets to another person and our stockholders immediately prior to such transaction own less than 50% of the aggregate voting power of the acquiring entity immediately after the transaction), then all shares of Preferred Stock shall, upon consummation of such change of control transaction, to the extent that we are not the surviving entity, automatically without any further action of any holder thereof, be converted into the Alternate Consideration; provided, however, that such Alternate Consideration shall be structured such that the holder is not required to beneficially own more than 4.99% of us or the surviving entity, as the case may be.

Exchange Listing. We do not plan on making an application to list the Preferred Stock on The NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system. Our common stock issuable upon conversion of the Preferred Stock is currently listed on the OTCQB under the symbol "NAOV," and has been approved for listing on The NASDAQ Capital Market under the symbol "NAOV."

Transfer Agent and Registrar. The transfer agent and registrar for our Preferred Stock is is VStock Transfer, LLC. The transfer agent's address is 18 Lafayette Place, Woodmere, New York 11598.

Warrants Being Issued in this Offering

The following is a brief summary of the material terms of the warrants offered pursuant to this prospectus and is subject in all respects to the provisions contained in the warrants, the form of which is filed as an exhibit to this prospectus. You should review a copy of the form of warrant for the complete description of the terms and conditions of the warrants being issued in this offering.

Form. The warrants will be issued in book-entry form under a warrant agent agreement between VStock Transfer, LLC, as warrant agent, and us, and shall initially be represented by one or more book-entry certificates deposited with DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. You should review a copy of the form of warrant, which is attached as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions of the warrants.

Exercisability. The warrants are exercisable at any time after the date of issuance, and at any time up to 5:00 p.m., New York City time, on the date that is five years after the date on which such warrants were issued, at which time any unexercised warrants will expire and cease to be exercisable. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise.

Fractional Shares. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Exercise Limitation. A holder 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 4.99% of the number of shares of our 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 such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until the 61st day after such notice to us.

Cashless Exercise. At any time when a registration statement covering the issuance of the shares of common stock issuable upon exercise of the warrants is not effective, the holder may, at its option, exercise its warrants on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of our common stock purchasable upon such exercise.

Exercise Price; Anti-Dilution. The initial exercise price per share of common stock purchasable upon exercise of the warrants is \$6.95 per full share of common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent. There is currently no trading market for the warrants and a trading market may not ever develop.

Exchange Listing. We do not plan on making an application to list the warrants on The NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system. Our common stock underlying the warrants is currently listed on the OTCQB under the symbol "NAOV," and has been approved for listing on The NASDAQ Capital Market under the symbol "NAOV."

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

We, with the consent of the warrant holders holding all of the then outstanding warrants (as measured by the number of shares of common stock underlying such warrants), may increase the exercise price, shorten the expiration date and amend all other warrant terms.

Warrants

\$3.00 and \$6.00 Two-Year Warrants

In connection with our January 29, 2015 securities purchase agreements, we issued, in January and February 2015, Two-Year Warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of \$3.00 per share and Two-Year Warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of \$6.00 per share. The Two-Year Warrants contain customary anti-dilution protections. The holders of such Two-Year Warrants have the right to exercise the Two-Year Warrants by means of a cashless exercise if after six months there is no effective registration statement under the Securities Act of 1933, as amended, registering the resale of the shares underlying the Two-Year Warrants. Upon the occurrence of certain change of control transactions, then any holder of the Two-Year Warrants shall, upon exercise, have the right to acquire the same securities as if it had exercised the Two-Year Warrants immediately before the date on which a record is taken for such transaction, or, if no such record is taken, the date as of which the record holders of shares of common stock are to be determined for the participation in such transaction. These Two-Year Warrants include provisions that block exercise if such exercise will result in the holder having beneficial ownership of more than 4.99% of our common stock in the case of one holder and 9.99% of our common stock in the case of all other holders. The Two-Year Warrants initially had a term of two years.

On January 27, 2017, we entered into amendments to the Two-Year Warrants. Pursuant to the amendments, the Two-Year Warrants to purchase 266,667 shares of common stock at \$3.00 per share and the Two-Year Warrants to purchase 266,667 shares of common stock at \$6.00 per share will expire on January 29, 2019, and the Two-Year Warrants to purchase 140,000 shares of common stock at \$3.00 per share and the Two-Year Warrants to purchase 140,000 shares of common stock at \$6.00 per share will expire on February 10, 2019, and the Two-Year Warrants to purchase 13,333 shares of common stock at \$3.00 per share and Two-Year Warrants to purchase 13,333 shares of common stock at \$6.00 per share will expire on February 23, 2019. The exercise prices and all other terms of the original Two-Year Warrants remain the same.

March 2015 Warrants

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 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 warrants will expire on March 25, 2020.

April 2015 Warrants

On April 10, 2015, automatically upon the effectiveness of the registration statement on Form 10 and our becoming a public reporting company, warrants which were previously convertible into series B-2 preferred stock were converted into warrants to purchase up to an aggregate of 331,293 shares of common stock at an exercise price of \$1.393. The warrants are otherwise identical to the warrants which were convertible into series B-2 preferred stock. The warrants contain customary anti-dilution protection. The holders of such warrants have the right to exercise the warrants by means of a cashless exercise. Upon the occurrence of certain change of control transactions, then any holder of the warrants shall, upon exercise, have the right to acquire the same securities as if it had exercised the warrants immediately before the consummation of such transaction. The warrants expire on November 15, 2018. Certain of these 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.

2017 Warrants

In 2017, we completed a series of bridge financings pursuant to which we have received aggregate proceeds of \$1,380,000 in exchange for convertible promissory notes in the aggregate principal amount of \$1,380,000. In connection with such bridge financings, as of September 11, 2017, we have issued 2017 Warrants to purchase an aggregate of 552,000 shares of common stock as follows: on March 1, 2017, we issued 2017 Warrants to purchase 100,000 shares of our common stock; on March 23, 2017, we issued 2017 Warrants to purchase 40,000 shares of common stock, on May 3, we issued 2017 Warrants to purchase 52,000 shares of common stock, on May 28, we issued 2017 Warrants to purchase 10,000 shares of common stock, on June 2, we issued 2017 Warrants to purchase 10,000 shares of common stock, on June 8, we issued 2017 Warrants to purchase 200,000 shares of our common stock, on August 25, we issued 2017 Warrants to purchase 80,000 shares of our common stock, and on September 21, 2017 we issued 2017 Warrants to purchase 60,000 shares of our common stock,

The 2017 Warrants are immediately exercisable and expires on the seven year anniversary of the date of issuance, and may be exercised on a cashless basis if there is no effective registration statement registering the resale of the underlying shares after the six month anniversary of the issuance date of the 2017 Warrants. The exercise price is \$5.90, which 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 2017 Warrants will not have the right to exercise any portion of its 2017 Warrants 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 2017 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.

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

Delaware Anti-Takeover Law

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

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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

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

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

Certificate of Incorporation and Bylaws

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, without further action by the stockholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of a majority of the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships (the “Whole Board”);
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of stockholders may be called only by a resolution adopted by a majority of the Whole Board; and
- set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors and with regard to business to be brought before a meeting of stockholders.

UNDERWRITING

We have entered into an underwriting agreement with Dawson James Securities, Inc. with respect to the common stock and Preferred Stock and accompanying warrants being offered. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase from us on a firm commitment basis, the number of shares of common stock (or Preferred Stock) and warrants set forth opposite its name in the table below.

Underwriter	Number of Shares (1)	Number of Warrants
Dawson James Securities, Inc.	1,020,407	765,305
Viewtrade Securities, Inc.	204,081	153,061
Total	1,224,488	918,366

(1) Includes both common stock and Preferred Stock as determined by the underwriters. Purchasers, if any, whose purchase of our common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, will have the opportunity, in lieu of purchasing common stock, to purchase Preferred Stock.

The underwriters are committed to purchase all the common stock (or Preferred Stock) and warrants offered by us if they purchase any such securities. The underwriters are not obligated to purchase the common stock or warrants covered by the underwriters' over-allotment option described below. The underwriters are offering the common stock (or Preferred Stock) or warrants, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted to the underwriters an option to purchase up to 183,673 additional shares of common stock (or up to 184 additional shares of Preferred Stock) and/or warrants to purchase up to an aggregate of 137,755 shares of common stock at an exercise price of \$6.95 per share, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions. The underwriters may exercise this option for 45 days from the date of this prospectus solely to cover sales of common stock and warrants by the underwriters in excess of the total number set forth in the table above. We will pay the expenses associated with the exercise of the over-allotment option. Dawson James Securities, Inc., its officers and its registered representatives may participate in this offering on the same terms and conditions as the investors participating in this offering.

Discounts and Commissions

The underwriters propose to offer to the public the common stock (or Preferred Stock) and the warrants purchased pursuant to the underwriting agreement at the public offering price per share of common stock and accompanying warrant on the cover page of this prospectus. The underwriters may offer some of the common stock (or Preferred Stock) and warrants to other securities dealers at such price less a concession not to exceed \$0.235 per share and accompanying warrant. After the shares and warrants are released for sale to the public, the underwriters may change the offering price and other selling terms at various times.

The factors considered in determining the public offering price included the recent market price of our common stock, the general condition of the securities market at the time of this offering, the history of, and the prospects for, the industry in which we compete, our past and present operations and our prospects for future revenues.

The following table shows the per share and accompanying warrant and total underwriting discounts and commissions we will pay in connection with the sale of the shares and the warrants.

	Per Share and Warrant	Total Without Over- Allotment Option	Maximum Total With Over-Allotment Option
Public offering price	\$ 4.90	\$ 5,999,991.20	\$ 6,899,989.88
Underwriting discounts and commissions	\$.392	\$ 479,999.30	\$ 551,999.19
Proceeds, before expenses, to us	\$ 4.508	\$ 5,519,991.90	\$ 6,347,990.69

We have also agreed to reimburse the underwriters for their expenses in connection with this offering, up to \$107,500, of which we previously agreed to advance \$10,000 for such expense to the underwriters. We estimate the total expenses of this offering which will be payable by us, excluding the underwriting discount and the underwriters' expenses payable by us, will be approximately \$469,000. After deducting the underwriting discount and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$5.1 million.

Right of First Refusal

Provided this offering is completed, for a period of twelve months from the closing date of this offering, Dawson James Securities, Inc. has a right of first refusal to act as our exclusive placement agent or lead underwriter and sole book runner, as applicable, in the event we decide to pursue an offering of our equity, equity-linked or debt securities during such period.

Underwriters' Unit Purchase Option

We have also agreed to issue to the underwriters' a unit purchase option to purchase a number of our securities equal to 5% of the securities and sold in this offering. The underwriters' unit purchase option will have an exercise price equal to 125% of the public offering price of the combination of shares and warrants set forth on the cover of this prospectus (or \$6.125 per share and accompanying warrant) and may be exercised on a cashless basis. The underwriters' unit purchase option is not redeemable by us. This prospectus also covers the sale of the underwriters' unit purchase option and the shares of common stock and warrants (and shares of common stock underlying such warrants) issuable upon the exercise of the underwriters' unit purchase option. The underwriters' unit purchase option and the underlying securities have been deemed compensation by FINRA, and are therefore subject to FINRA Rule 5110(g)(1). In accordance with FINRA Rule 5110(g)(1), neither the underwriters' unit purchase option nor any securities issued upon exercise of the underwriters' unit purchase option may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which the underwriters' unit purchase option is being issued, except the transfer of any security:

- by operation of law or by reason of reorganization of our company;
- to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period;
- if the aggregate amount of our securities held by either an underwriter or a related person do not exceed 1% of the securities being offered;
- that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

In addition, in accordance with FINRA Rule 5110(f)(2)(G), the underwriters' warrant may not contain certain anti-dilution terms.

Lock-up Agreements

The underwriting agreement provides that we will agree, subject to certain exceptions, for a period of 180 days from the date of the underwriting agreement, that we will not (a) offer, sell, or otherwise transfer or dispose of, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock, except for the exercise of outstanding options and warrants, securities issued for compensation, shares we are contractually obligated to issue; or (b) file or caused to be filed any registration statement relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock.

Pursuant to the terms of the underwriting agreement, our officers and directors have agreed, subject to certain exceptions, from the date of this prospectus until 180 days after the closing of this offering, not to sell, offer to sell, contract or agree to sell, hypothecate, pledge, grant any option to purchase, make any short sale or otherwise dispose of or agree to dispose of, directly or indirectly, any common stock or common stock equivalents, establish or otherwise enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the shares owned by the officers and directors or make any demand for or exercise any registration right with respect to any common stock or common stock equivalents.

Indemnification

We have agreed to indemnify the underwriters and certain other persons against certain liabilities relating to or arising out of the underwriters' activities under the underwriting agreement. We have also agreed to contribute to payments that the underwriters may be required to make in respect of such liabilities.

Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional common stock in the offering pursuant to the exercise of their over-allotment option to purchase only additional shares. The underwriters may close out any covered short position by either exercising the over-allotment option or purchasing common stock in the open market. In determining the source of common stock to close out the covered short position, the underwriters will consider, among other things, the price of common stock available for purchase in the open market as compared to the price at which they may purchase common stock through the over-allotment option. "Naked" short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common shares or preventing or retarding a decline in the market price of our common shares. As result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common shares, including the imposition of penalty bids. This means that if the representative of the underwriters purchases common stock in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

Electronic Offer

This prospectus supplement and the accompanying prospectus may be made available in electronic format on Internet sites or through other online services maintained by the underwriters or its affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. Other than this prospectus supplement and the accompanying prospectus in electronic format, any information on the underwriters' or its affiliates' websites and any information contained in any other website maintained by the underwriters or any affiliate of the underwriters is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other

The underwriters or their affiliates may engage in transactions with, and may perform, from time to time, investment banking and advisory services for us in the ordinary course of their business and for which they would receive customary fees and expenses. However, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Haynes and Boone, LLP, New York, New York. Schiff Hardin, LLP, Washington DC, is acting as counsel for the underwriters in connection with the securities offered hereby. Haynes and Boone, LLP owns 100,000 shares of our common stock.

EXPERTS

The financial statements as of December 31, 2016 and 2015 and for each of the two years in the period ended December 31, 2016 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to our ability to continue as a going concern as described in Note 1 to the financial statements) of Kost Forer Gabbay & Kasierer, an independent registered public accounting firm and a member of Ernst & Young Global, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and in accordance therewith file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements and other information can be read and copied at the Securities and Exchange Commission's Public Reference Room at 100 F Street, N.W., Washington, D.C. 20549, on official business days during the hours of 10:00 am to 3:00 pm. Please call the Securities and Exchange Commission at 1-800-732-0330 for further information on the operation of the Public Reference Room. In addition, the Securities and Exchange Commission maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The address of the Securities and Exchange Commission's website is www.sec.gov.

We make available free of charge on or through our website at www.nanovibronix.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the Securities and Exchange Commission.

We have filed with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the Securities and Exchange Commission at the address listed above, or for free at www.sec.gov. The registration statement is also available on our website, www.nanovibronix.com.

We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS

U.S. DOLLARS IN THOUSANDS

INDEX

	<u>Page</u>
Audited Financial Statements as of December 31, 2016	
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Consolidated Balance Sheets</u>	<u>F-3</u>
<u>Consolidated Statements of Comprehensive Loss</u>	<u>F-5</u>
<u>Statements of Changes in Stockholders' Deficiency</u>	<u>F-6</u>
<u>Consolidated Statements of Cash Flows</u>	<u>F-7</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-8</u>
Unaudited Interim Financial Statements	
<u>Consolidated Balance Sheets (unaudited)</u>	<u>F-29</u>
<u>Consolidated Statements of Comprehensive Loss (unaudited)</u>	<u>F-31</u>
<u>Statements of Changes in Stockholders' Deficiency (unaudited)</u>	<u>F-32</u>
<u>Consolidated Statements of Cash Flows (unaudited)</u>	<u>F-33</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-34</u>



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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

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
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
<u>Total current assets</u>	<u>221</u>	<u>1,776</u>
NON-CURRENT ASSETS:		
Long-term prepaid expense	5	-
Severance pay fund	257	197
Property and equipment, net (Note 5)	11	10
<u>Total non-current assets</u>	<u>273</u>	<u>207</u>
<u>Total assets</u>	<u>\$ 494</u>	<u>\$ 1,983</u>

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

NANOVIBRONIX INC. AND ITS SUBSIDIARY

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.

NANOVIBRONIX INC. AND ITS SUBSIDIARY

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	<u>1,951,261</u>	<u>\$ 2</u>	<u>2,611,328</u>	<u>\$ 2</u>	<u>\$ 19,521</u>	<u>\$ (19,734)</u>	<u>\$ (209)</u>
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	<u>1,951,261</u>	<u>2</u>	<u>2,632,710</u>	<u>2</u>	<u>20,073</u>	<u>(22,576)</u>	<u>(2,499)</u>

*) 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	<u>(1,533)</u>	<u>(1,480)</u>
Cash flows from investment activities:		
Purchase of property and equipment	(8)	(1)
Net cash used in investment activities	<u>(8)</u>	<u>(1)</u>
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	<u>33</u>	<u>3,005</u>
Increase (Decrease) in cash and cash equivalents	(1,508)	1,524
Cash and cash equivalents at the beginning of the period	<u>1,614</u>	<u>90</u>
Cash and cash equivalents at the end of the period	<u>\$ 106</u>	<u>\$ 1,614</u>
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	<u>\$ -</u>	<u>\$ 5,066</u>

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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:

	<u>%</u>
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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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).

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Prepaid expenses	\$ 34	\$ 50
Other accounts receivable	8	36
	<u>\$ 42</u>	<u>\$ 86</u>

NOTE 4:- INVENTORIES

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Raw materials	\$ 44	\$ 53
Work in process	5	4
Finished goods	18	14
	<u>\$ 67</u>	<u>\$ 71</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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
	<u>51</u>	<u>110</u>
Accumulated depreciation:		
Computers and peripheral equipment	38	91
Office furniture and equipment	2	9
	<u>40</u>	<u>100</u>
Depreciated cost	<u>\$ 11</u>	<u>\$ 10</u>

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
	<u>483</u>	<u>239</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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	<u>\$ 2,079</u>	<u>\$ 1,696</u>

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	<u>\$ 15</u>

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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:

<u>Issuance date</u>	<u>Options for Common stock</u>	<u>Weighted Average exercise price per share</u>	<u>Options exercisable</u>	<u>Expiration date</u>
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:

	<u>Year ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
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%.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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
	<u>\$ 2,714</u>	<u>\$ 2,856</u>

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	<u>\$ -</u>	<u>\$ -</u>

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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	<u>\$ 170</u>	<u>\$ 97</u>

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
	<u>\$ 398</u>	<u>\$ 1,432</u>

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
	<u>\$ 229</u>	<u>\$ 147</u>

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 its 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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").

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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.

CONSOLIDATED BALANCE SHEETS (Unaudited)

U.S. dollars in thousands

	June 30, 2017	December 31 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 215	\$ 106
Trade receivables	3	6
Prepaid expenses and other accounts receivable	47	42
Inventories	82	67
Total current assets	347	221
NON-CURRENT ASSETS:		
Long-term prepaid expense	110	5
Severance pay fund	292	257
Property and equipment, net	8	11
Total non-current assets	410	273
Total assets	\$ 757	\$ 494

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

CONSOLIDATED BALANCE SHEETS (Unaudited)

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

	June 30, 2017	December 31, 2016
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Trade payables	\$ 223	\$ 82
Other accounts payable	531	483
Total current liabilities	754	565
LONG-TERM LIABILITIES:		
Convertible promissory notes	713	—
Warrants to purchase Common stock	1,948	2,079
Accrued severance pay	393	349
Total long-term liabilities	3,054	2,428
COMMITMENTS AND CONTINGENT LIABILITIES		
STOCKHOLDERS' DEFICIENCY:		
Stock capital -		
Common stock of \$ 0.001 par value -		
Authorized: 24,000,000 shares at June 30, 2017 and December 31, 2016; Issued and outstanding: 2,632,710 and 2,632,710 shares at June 30, 2017 and December 31, 2016, respectively.	2	2
Series C Preferred stock of \$ 0.001 par value -		
Authorized: 5,500,000 shares at June 30, 2017 and December 31, 2016; Issued and outstanding: 1,951,261 shares at June 30, 2017 and December 31, 2016, respectively	2	2
Additional paid-in capital	22,087	20,073
Accumulated deficit	(25,142)	(22,576)
Total stockholders' deficiency	(3,051)	(2,499)
Total liabilities and stockholders' deficiency	\$ 757	\$ 494

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

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

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

	Six months ended June 30,		Three months ended June 30,	
	2017	2016	2017	2016
Revenues	\$ 104	\$ 119	\$ 52	\$ 62
Cost of revenues	34	49	18	22
Gross profit	70	70	34	40
Operating expenses:				
Research and development	314	287	164	173
Selling and marketing	200	271	106	126
General and administrative	1,017	442	424	197
<u>Total operating expenses</u>	<u>1,531</u>	<u>1,000</u>	<u>694</u>	<u>496</u>
Operating loss	(1,461)	(930)	(660)	(456)
Financial expense, net	242	156	178	144
Loss before taxes on income	(1,703)	(1,086)	(838)	(600)
Taxes on income	22	19	11	10
Loss and total comprehensive loss	<u>\$ (1,725)</u>	<u>\$ (1,105)</u>	<u>\$ (849)</u>	<u>\$ (610)</u>
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2017	\$ 841	\$ —	\$ —	\$ —
Total comprehensive loss attributable to holders of Common Stock and Preferred C stock	<u>\$ (2,566)</u>	<u>\$ (1,105)</u>	<u>\$ (849)</u>	<u>\$ (610)</u>
Common stock and Preferred C stock basic and diluted loss per share	<u>\$ (0.56)</u>	<u>\$ (0.24)</u>	<u>\$ (0.19)</u>	<u>\$ (0.13)</u>
Weighted average number of shares of Common stock and Preferred C stock used in computing basic and diluted loss per share	<u>4,583,971</u>	<u>4,573,773</u>	<u>4,583,971</u>	<u>4,574,971</u>

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY (Unaudited)

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

	Preferred C stocks		Common stocks		Additional paid-in capital	Accumulated deficit	Total stockholders' deficiency
	Number	Amount	Number	Amount			
Balance as of January 1, 2016	<u>1,951,261</u>	<u>\$ 2</u>	<u>2,611,328</u>	<u>\$ 2</u>	<u>\$ 19,521</u>	<u>\$ (19,734)</u>	<u>\$ (209)</u>
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	<u>1,951,261</u>	<u>2</u>	<u>2,632,710</u>	<u>2</u>	<u>20,073</u>	<u>(22,576)</u>	<u>(2,499)</u>
Stock-based compensation related to options granted to employees	—	—	—	—	536	—	536
Issuance of warrants to Common stock	—	—	—	—	637	—	637
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2017	—	—	—	—	841	(841)	—
Total comprehensive loss	—	—	—	—	—	(1,725)	(1,725)
Balance as of June 30, 2017 (unaudited)	<u>1,951,261</u>	<u>2</u>	<u>2,632,710</u>	<u>2</u>	<u>22,087</u>	<u>(25,142)</u>	<u>(3,051)</u>

*) Represents an amount lower than \$ 1.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

U.S. dollars in thousands

	Six months ended June 30,	
	2017	2016
Cash flows from operating activities:		
Loss	\$ (1,725)	\$ (1,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5	4
Stock-based compensation	536	121
Benefit component of Promissory Notes	320	—
Revaluation of warrants to purchase Common stock	(131)	147
Decrease (increase) in trade receivables	3	(2)
Increase in prepaid expenses and other accounts receivable	(110)	(37)
Decrease (increase) in inventories	(15)	12
Increase (decrease) in trade payables	141	(30)
Increase in other accounts payable	48	50
Increase in accrued severance pay, net	9	—
Net cash used in operating activities	<u>(919)</u>	<u>(840)</u>
Cash flows from investment activities:		
Purchase of property and equipment	<u>(2)</u>	<u>(8)</u>
Net cash used in investment activities	<u>(2)</u>	<u>(8)</u>
Cash flows from financing activities:		
Proceeds from issuance of Convertible Promissory Notes and warrants	1,030	—
Proceeds from exercise of options	<u>—</u>	<u>33</u>
Net cash provided by financing activities	<u>1,030</u>	<u>33</u>
Increase (decrease) in cash and cash equivalents	109	(815)
Cash and cash equivalents at the beginning of the period	<u>106</u>	<u>1,614</u>
Cash and cash equivalents at the end of the period	<u>\$ 215</u>	<u>\$ 799</u>
Supplemental information and disclosure of non-cash financing transactions:		
Carve out of warrants' fair value from Convertible Promissory Notes	<u>\$ 637</u>	<u>\$ —</u>

The accompanying notes are an integral part of the interim 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 \$1,725 during the six month period ended June 30, 2017, has an accumulated deficit of \$25,142 as of June 30, 2017 and accumulated negative cash flow from operating activities in the amount of \$919. 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.

In the opinion of management, the accompanying unaudited interim consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2016, as found in the Company’s Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on July 26, 2017. The balance sheet for December 31, 2016 was derived from the Company’s audited financial statements for the year ended December 31, 2016. The results of operations for the six and three months ended June 30, 2017 are not necessarily indicative of results that could be expected for the entire fiscal year.

- 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 significant accounting policies applied in the annual consolidated financial statements of the Company as of December 31, 2016 are applied consistently in these financial statements.

NOTE 3:- UNAUDITED INTERIM FINANCIAL STATEMENTS

The accompanying unaudited consolidated financial statements as of June 30, 2017 have been prepared in accordance with the U.S. generally accepted accounting principles for interim financial information. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements. In the opinion of management, the unaudited interim consolidated financial statements include all adjustments of a normal recurring nature necessary for a fair presentation of the Company’s consolidated financial position as of June 30, 2017, the Company’s consolidated results of operation for the six and three months ended June 30, 2017 and the Company’s consolidated cash flows for the six months ended June 30, 2017.

NOTE 4:- FAIR VALUE MEASUREMENTS

ASC 820, “Fair Value Measurements and Disclosures” (“ASC 820”), defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

ASC 820 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. ASC 820 establishes three levels of inputs that may be used to measure fair value.

- Level 1 - quoted prices in active markets for identical assets or liabilities;
- Level 2 - inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or
- Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

During February 2013, the Company signed a convertible Promissory Notes agreement (the "Agreement") pursuant to which the Company issued secured convertible Promissory Notes (the "Notes") to certain investors on February 5, 2013. On each of March 28, 2013, June 3, 2013, August 5, 2013, October 7, 2013, December 9, 2013, February 6, 2014, April 1, 2014, May 15, 2014, June 16, 2014, August 7, 2014, September 7, 2014, October 13, 2014, November 19, 2014 and December 11, 2014, the Agreement and the Notes were amended and restated to increase the principal amount by \$100. In addition, with each amendment, the Company issued to the holders of the Note warrants to purchase up to 37,594 shares of common stock in consideration for an additional \$100 per amendment. 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 within a period of five years, based on the issuance date.

In April 2015, the holders of the Notes elected to convert the outstanding principal and interest thereunder into shares of the Company's series C preferred stock. On that date, an aggregate principal balance of \$1,500 and \$106 in accrued interest were converted into 603,769 shares of series C preferred stock. The shares of series C preferred stock were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold pursuant to the exemption from registration under the Securities Act of 1933, as amended, provided by Section 3(a)(9) of the Securities Act of 1933, as amended.

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 value being recognized in the Company's consolidated statement of comprehensive loss as financial income or expense.

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

	June 30,	
	2017	2016
Dividend yield ⁽¹⁾	0%	0%
Expected volatility ⁽²⁾	50.16%-58.28%	63.2%-67.1%
Risk-free interest ⁽³⁾	1.17%-1.47%	0.77%-0.88%
Expected term (years) ⁽⁴⁾	0.6-2.4	1.7-3.6

- (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 a term that is equivalent to the expected term of the warrants.
- (3) Risk-free interest - was based on yield rate of non-index linked U.S. Federal Reserve treasury stock.
- (4) Expected term - was based on the maturity date of the warrants.

Fair value measurement using significant unobservable inputs (Level 3):

	Fair value of warrants to Common stock
Balance at January 1, 2017	\$ 2,079
Change in fair value of warrants	(131)
Balance at June 30, 2017	\$ 1,948

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

Effective as of 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. Since substantially all of the warrants to purchase 840,000 shares of common stock subject to the Warrant Amendment are held by the Company’s stockholders, the Warrant Amendment was accounted for as “deemed dividend,” which was measured at the amount equal to the incremental value reflecting the change in the fair value of the warrants before and after the Warrant Amendment. Accordingly, a deemed dividend in the amount of \$841 was recorded to the Statement of Changes in Stockholders’ Deficiency as an increase in additional paid-in capital with a corresponding increase in the accumulated deficit.

In March 2017, the Company completed a bridge financing, pursuant to which the Company received from four investors \$350 of loans and issued to the investors convertible promissory notes (the “2017 Notes”) in an aggregate principal amount of \$350 and seven-year warrants (the “Warrants”) to purchase an aggregate of 140,000 shares of common stock at an exercise price of \$5.90 per share (the “Exercise Price”) (see Note 5). The Company measured the Warrants at fair value on their issuance date by applying the Black-Scholes options pricing model, according to the following assumptions:

	June 30, 2017
Dividend yield ⁽¹⁾	0%
Expected volatility ⁽²⁾	65.16%-65.80%
Risk-free interest ⁽³⁾	2.23%-2.27%
Expected term (years) ⁽⁴⁾	7

- (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 a term that is equivalent to the expected term of the warrants.
- (3) Risk-free interest – was based on yield rate of non-index linked U.S. Federal Reserve treasury stock.
- (4) Expected term - was based on the maturity date of the warrants.

In May and June 2017, the Company completed additional bridge financings, pursuant to which the Company received from five investors \$680 of loans and issued to the investors 2017 Notes in an aggregate principal amount of \$680 and Warrants to purchase an aggregate of 272,000 shares of common stock at the Exercise Price (see Note 5). The Company measured the Warrants at fair value on their issuance date by applying the Black-Scholes options pricing model, according to the following assumptions:

	June 30, 2017
Dividend yield ⁽¹⁾	0%
Expected volatility ⁽²⁾	65.54%-65.85%
Risk-free interest ⁽³⁾	2%-2.14%
Expected term (years) ⁽⁴⁾	7

- (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 a term that is equivalent to the expected term of the warrants.
- (3) Risk-free interest – was based on yield rate of non-index linked U.S. Federal Reserve treasury stock.
- (4) Expected term - was based on the maturity date of the warrants.

In addition, the Company’s financial instruments also include cash and cash equivalents, trade receivables, prepaid expenses and other accounts receivable, trade payables and other accounts payable. The fair value of these financial instruments was not materially different from their carrying values as of June 30, 2017 due to the short-term maturities of such instruments.

NOTE 5:- RECENTLY ISSUED ACCOUNTING STANDARDS

1. In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. 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 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. The Company is planning to adopt this ASU on January 1, 2018 under the modified retrospective approach, which will result in a cumulative adjustment to retained earnings. The Company expects that, as a result of the adoption of this ASU, the timing of recognizing revenue from sales of products to its distributors under agreements that will allow certain rights of return and other special rights will be generally earlier than under the existing revenue recognition guidance. The Company continues to evaluate the requirements of the standard, which are currently not expected to have a material effect on the Company’s financial statements.
2. In May 2017 the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU No. 2017-09 is effective for financial statements issued for annual reporting periods beginning after December 15, 2017 and interim periods within those years. Earlier application is permitted. The adoption of the new requirements of ASU No. 2017-09 are not expected to have a material impact on the Company’s consolidated financial position or results of operations.
3. In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Non-public Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception*. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II simply replaces the indefinite deferral for certain mandatorily redeemable non-controlling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification (ASC) Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. This ASU is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of the standard may have on its consolidated financial statements.

NOTE 6:- CONVERTIBLE PROMISSORY NOTES

Since March 1, 2017, we have completed a series of bridge financings pursuant to which we have received from accredited investors aggregate proceeds of \$1,030 in exchange for 2017 Notes in the aggregate principal amount of \$1,030, and seven-year Warrants to purchase an aggregate of 412,000 shares of common stock at an exercise price of \$5.90 per share.

The principal amount and all accrued but unpaid interest on the 2017 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 2017 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 2017 Notes and interest then accrued and unpaid thereon, or (b) shares of common stock or Series C Convertible Preferred Stock of the Company, at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company as of the Maturity Date, as determined in good faith by the Company's board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, as of the Maturity Date on a fully diluted basis, and (y) \$5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the capital stock of the Company. Upon consummation of a Qualified Financing, the investors may elect to have the outstanding principal and accrued but unpaid interest thereon converted into shares of the same class and series of equity securities sold in such Qualified Financing, provided that the investor may elect to receive shares of Series C Convertible Preferred Stock instead of shares of common stock, to the extent that common stock are issued in such Qualified Financing, at a price per share equal to the lesser of: (a) 80% of the price per share at which such securities are sold in such Qualified Financing and (b) \$5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the Company's capital stock. If there is a change of control and the 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 2017 Notes and interest then accrued and unpaid thereon, or (b) convert the 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 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.

As a result of issuing the warrants and as a result of the discount on the conversion price of the 2017 Notes, the Company recorded in the six months and three months ended June 30, 2017 a benefit component in the amount of \$637 and \$415, respectively, to be amortized over the expected life of the 2017 Notes.

NOTE 7:- STOCKHOLDERS' DEFICIENCY

Stock based compensation

During the six and three-month period ended June 30, 2017 the Company recorded share based compensation in a total amount of \$536 and \$185, respectively. During the six and three-month period ended June 30, 2016 the Company recorded share based compensation in a total amount of \$121 and \$56, respectively.

In connection with the resignation of a director from our board of directors, on March 30, 2017, we amended the option agreement, dated March 25, 2015, we entered into an agreement with the resigned director 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, 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 the director in 2016 so that it will be fully vested as of March 30, 2017, and (ii) permit the director 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. This modification resulted in additional share based compensation expense of \$98 and \$0 in the six and three months ended June 30, 2017.

As of June 30, 2017, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$992, which is expected to be recognized over a weighted average period of approximately 2.8 years.

NOTE 8:- COMMITMENTS AND CONTINGENT LIABILITIES

- a. The Company leases office facilities and motor vehicles under operating leases, which expire on various dates, the latest of which expired on July 31, 2017.

Future minimum lease commitments under non-cancelable operating lease agreements as of June 30, 2017 are as follows:

Six months ending December 31,	Operating leases
2017	\$ 2
Total	\$ 2

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 \$13 and \$15 for the six months and \$7 and \$7 for the three months ended June 30, 2017 and 2016, respectively.

Motor vehicle leases and related expenses were \$9 and \$5 for the six months and \$4 and \$3 for the three months ended June 30, 2017 and 2016, 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 June 30, 2017, there are no sales from the funded project and the Company has a contingent obligation to pay royalties in the principal amount of approximately \$ 492. 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 9:- LOSS PER SHARE

All outstanding share options and warrants for the six and the three months ended June 30, 2017 and 2016 have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented.

NOTE 10:- GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

Summary information about geographic areas:

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

	Six months ended		Three months ended	
	June 30,		June 30,	
	2017	2016	2017	2016
United States	\$ 40	\$ 36	\$ 19	\$ 17
Europe	29	38	13	17
Israel	1	7	1	6
India	8	9	5	3
Rest of the world	26	29	14	19
	<u>\$ 104</u>	<u>\$ 119</u>	<u>\$ 52</u>	<u>\$ 62</u>

During the six and three month period ended June 30, 2017, revenues from distributors accounted for 36% and 37% of total revenues. During the six and three month period ended June 30, 2016, revenues from distributors accounted for 33% and 27% of total revenues.

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

NOTE 11:- 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. For its interim consolidated financial statements as of June 30, 2017 (unaudited) and for the three months period then ended (unaudited), the Company evaluated subsequent events through August 14, 2017 the date that the consolidated financial statements were issued.



NanoVibronix, Inc.

**1,224,488 Shares of
Common Stock,
Warrants to Purchase up to 918,366 Shares of Common Stock
(918,366 Shares of Common Stock Underlying the Warrants)
and
1,225 Shares of Series D Convertible Preferred Stock
(1,224,488 Shares of Common Stock Underlying the Series D Convertible Preferred Stock)**

PROSPECTUS

Dawson James Securities, Inc.

November 1, 2017
