

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ENDRA Life Sciences Inc.

Form: 10-K

Date Filed: 2018-03-20

Corporate Issuer CIK: 1681682

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2017

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

For the transition period from _____ to _____

Commission file number: 001-37969

ENDRA Life Sciences Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

26-0579295
(I.R.S. Employer Identification No.)

3600 Green Court, Suite 350, Ann Arbor, MI
(Address of Principal Executive Offices)

48105-1570
(Zip Code)

(734) 335-0468

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	The NASDAQ Stock Market LLC
Warrants, each to purchase one share of Common Stock	The NASDAQ Stock Market LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant, as of June 30, 2017, was approximately \$14,831,809 based on the closing sales price of the common stock on such date as reported on the NASDAQ Capital Market.

As of March 20, 2018, there were 3,923,027 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

ENDRA LIFE SCIENCES INC.
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Annual Report”) contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the “safe harbor” created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as “believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “seek,” “intend,” “plan,” “goal,” “project,” “estimate,” “anticipate,” “strategy,” “future,” “likely” or other comparable terms and references to future periods. All statements other than statements of historical facts included in this Annual Report regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding: expectations for revenues, cash flows and financial performance, the anticipated results of our development efforts and the timing for receipt of required regulatory approvals and product launches.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- our limited commercial experience, limited cash and history of losses;
- our ability to obtain adequate financing to fund our business operations in the future;
- our ability to achieve profitability;
- our ability to develop a commercially feasible application based on our Thermo-Acoustic Enhanced Ultrasound (“TAEUS”) technology;
- market acceptance of our technology;
- results of our human studies, which may be negative or inconclusive;
- our ability to find and maintain development partners;
- our reliance on collaborations and strategic alliances and licensing arrangements;
- the amount and nature of competition in our industry;
- our ability to protect our intellectual property;
- potential changes in the healthcare industry or third-party reimbursement practices;
- delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications for CE mark certification or FDA approval;
- our ability to obtain CE mark certification and secure required Food and Drug Administration (“FDA”) and other governmental approvals for our TAEUS applications;
- our ability to comply with regulation by various federal, state, local and foreign governmental agencies and to maintain necessary regulatory clearances or approvals; and
- the other risks and uncertainties described in the Risk Factors and in Management’s Discussion and Analysis of Financial Condition and Results of Operations sections of this Annual Report.

Any forward-looking statement made by us in this report is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

PART I

As used in this Annual Report, unless the context otherwise requires, the terms "ENDRA," "we," "us," "our," and the "Company" refer to ENDRA Life Sciences Inc., a Delaware corporation.

Item 1. Business

Overview

We have commercialized an enhanced ultrasound technology for the pre-clinical research market and are leveraging that expertise to develop technology for increasing the capabilities of clinical diagnostic ultrasound to broaden patient access to the safe diagnosis and treatment of a number of significant medical conditions in circumstances where expensive X-ray computed tomography, or CT, and magnetic resonance imaging, or MRI, technology is unavailable or impractical.

Since 2010, we have marketed and sold our Nexus 128 system, which combines light-based thermoacoustics and ultrasound, to address the imaging needs of researchers studying disease models in pre-clinical applications. Building on our expertise in thermoacoustics, we have developed a next-generation technology platform — Thermo Acoustic Enhanced Ultrasound, or TAEUS, which is intended to enhance the capability of clinical ultrasound technology and support the diagnosis and treatment of a number of significant medical conditions that require the use of expensive CT or MRI imaging or where imaging is not practical using existing technology. We believe that our TAEUS technology, which can be used with existing ultrasound equipment and incorporated into next-generation ultrasound systems, has the potential to make advanced imaging available in certain applications to a wider range of patients on a more cost-effective basis than is possible using existing CT and MRI technology. We expect to continue to sell our Nexus 128 system to maintain a base level of revenue, but believe the market potential for our clinical systems is much higher.

Diagnostic Imaging Technologies

Diagnostic imaging technologies such as CT, MRI and ultrasound allow physicians to look inside a person's body to guide treatment or gather information about medical conditions such as broken bones, cancers, signs of heart disease or internal bleeding. The type of imaging technology a physician uses depends on a patient's symptoms and the part of the body being examined. CT technology is well suited for viewing bone injuries, diagnosing lung and chest problems, and detecting cancers. MRI technology excels at examining soft tissue in ligament and tendon injuries, spinal cord injuries, and brain tumors. CT scans can take as little as 5 minutes, while an MRI scan can take up to 30 minutes.

Unfortunately, while CT and MRI systems are versatile and create high quality images, they are also expensive and not always accessible to patients. A CT system costs approximately \$1 million and an MRI system can cost up to \$3 million. CT and MRI systems are large and can weigh several tons, typically requiring significant modifications to existing healthcare facilities to safely handle the load. Because of their size and weight, CT and MRI systems are usually fixed-in-place at major medical facilities. As a result, they are less accessible to primary care and rural clinics, economically developing markets, and patient bedsides. As of 2013, there were only approximately 64,000 CT systems and 32,000 MRI systems in the world, approximately 50% of which were located in the U.S. and Japan.

While CT and MRI systems create high quality images, their use is not always practical. For example, the diagnosis and treatment of the estimated 1.4 billion patients suffering from Non-Alcoholic Fatty Liver Disease, or NAFLD, requires ongoing surveillance of the patients' livers to assess the progression of the disease and the efficacy of treatment. However, the use of CT and MRI systems to perform that surveillance is impractical for a number of reasons, including the high cost of the scan, the limited availability of CT and MRI systems and the required use of contrast agents, including those containing radioactive substances that can cause allergic reactions and reduced kidney functions. Patient exposure to the ionizing radiation generated by a CT system must be limited for safety reasons. Similarly, because of the strong magnetic field created by an MRI machine, patients with metal joint replacements or cardiac pacemakers cannot be imaged with an MRI system.

Because of CT and MRI's limited availability and practical limitations, a patient who would otherwise be a candidate for CT or MRI scanning must often rely on less effective or less practical methods. For example, MRI scans are not typically used to measure tissue temperature during thermoablative (temperature based) surgery. Instead, physicians use printed manufacturer guidelines to time the thermal surgery or insert surgical temperature probes in an attempt to guide treatment. As a result, the treatment is often imprecise or comes with additional risks, such as infection.

These limitations have led to a decrease in the number of CT scans. According to the American College of Radiology, the overall number of CT scans performed in the United States under Medicare Part B fell approximately 8% from 2009 to 2014. The decline in CT scans has been accompanied by increased use of alternative scanning technologies. The American College of Radiology reported that the overall number of ultrasound scans performed in the United States under Medicare Part B increased approximately 6% from 2009 to 2014. During the same period MRI usage increased by 5%, but remains significantly below the use of ultrasound technology, even in the United States.

Ultrasound Technology

An ultrasound machine transmits sound waves, which bounce off tissues, organs and blood in the body. The ultrasound machine captures these echoes and uses them to create an image. Ultrasound technology excels at imaging the structure of internal organs, muscles and bone surfaces. Due to its utility, cost-effectiveness and safety profile, ultrasound imaging is frequently used in a physician's examination room or at a patient's bedside as a first-line diagnostic tool, which has resulted in an overall increase in the number of ultrasound scans performed.

Ultrasound systems are more broadly available to patients than either CT or MRI systems. There are an estimated 925,000 ultrasound systems globally in use today. Ultrasound systems are relatively inexpensive compared to CT and MRI systems, with smaller portable ultrasound systems costing as little as \$10,000 and new cart-based ultrasound systems costing between \$75,000 and \$200,000. Ultrasound systems are also more mobile than CT and MRI systems and many are designed to be moved by an operator from room to room, or closer to patients. Ultrasound technology does not present the same safety concerns as CT and MRI technology, since ultrasound does not emit ionizing radiation and ultrasound contrast agents are considered to be generally safe.

However, ultrasound's imaging capabilities are more limited compared to CT and MRI technology. For example, ultrasound systems cannot measure tissue temperature during thermal ablation surgery, or quantify fat to diagnose early stage liver disease -- instances where CT and MRI systems are used.

Ultrasound Market

Sales of ultrasound diagnostic equipment were approximately \$4.4 billion globally in 2017 and are expected to grow at approximately 4.4% annually. There are an estimated 925,000 installed systems generating over 400 million annual diagnostic ultrasound procedures globally. Additionally, an estimated 30,000 to 50,000 new and replacement systems are sold into the market each year. These numbers include both portable and cart-based ultrasound systems, and cover all types of diagnostic ultrasound procedures, including systems intended for cardiology, prenatal and abdominal use. We do not intend to address low-cost, portable ultrasound systems and systems focused on applications, such as prenatal care, where we believe our TAEUS technology will not substantially impact patient care. Accordingly, we define our addressable market for one or more of our TAEUS applications at approximately 338,000 cart-based ultrasound systems currently in use throughout the world.

We believe that demand for ultrasound systems is driven primarily by the following factors:

- Population growth and age demographics that increase the demand for diagnostic screening for cancer, cardiology, and prenatal applications.
- Economic development broadening investment in healthcare in previously underserved markets such as China and Latin America, where ultrasound technology has significant appeal due to its price point and flexibility at point-of-care.
- Expanding ultrasound applications and improving image quality that drive demand for new ultrasound technologies, such as software enhancements, bi-axial probes, and dedicated single application systems.
- Positive insurance reimbursement rate trends for ultrasound diagnostics due to the technology's safety and cost-effectiveness.

Unmet Need

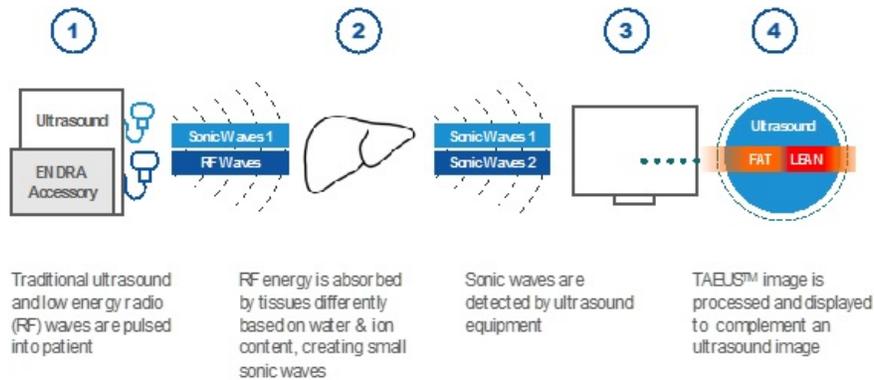
We believe that the limited availability of high-utility and cost-effective imaging technology represents a significant unmet medical need. We believe that expanding the capability of ultrasound technology to perform more of the imaging tasks presently available only on expensive CT and MRI systems will satisfy this unmet need.

Our Solutions

Our Thermo-Acoustic Enhanced Ultrasound, or TAEUS, technology, as well as our commercially available Nexus 128 system, use a pulsed energy source – near-infrared light and radio-frequency, or RF, respectively – to generate ultrasonic waves in tissue. These waves are then detected with ultrasound equipment and used to create high-contrast images using our proprietary algorithms. Unlike conventional ultrasound, which creates images based on the scattering properties of tissue, thermoacoustic imaging provides tissue absorption maps of the pulsed energy, similar to those generated by CT scans. Ultrasound is only utilized to transmit the absorption signal to the imaging system outside of the body.

Our TAEUS Technology Platform for Clinical Applications

To increase the utility of our thermoacoustic technology, in 2013 we began to develop our TAEUS technology platform. Unlike the near-infrared light pulses used in our Nexus 128 system (discussed below), our TAEUS technology uses RF pulses to stimulate tissues, using a small fraction of the energy transmitted into the body during an MRI scan. Using RF energy enables our TAEUS technology to penetrate deep into tissue, enabling the imaging of human anatomy at depths equivalent to those of conventional ultrasound. The RF pulses are absorbed by tissue and converted into ultrasound signals, which are detected by an external ultrasound receiver and a digital acquisition system that is part of the TAEUS system. The detected ultrasound is processed into images using our proprietary algorithms and displayed to complement conventional gray-scale ultrasound images. The TAEUS imaging process is illustrated below:



Our RF-based thermoacoustics are not adversely affected by blood-filled organs, enabling our TAEUS technology to be used in clinical liver applications, among others.

After approval, our TAEUS technology can be added as an accessory to existing ultrasound systems, helping to improve clinical decision-making on the front lines of patient care, without requiring new clinical workflows or large capital investments. We are also developing TAEUS for incorporation into new ultrasound systems, primarily through our collaboration with GE Healthcare, described more fully below.

We believe that our TAEUS technology has the potential to add a number of new capabilities to conventional ultrasound and thereby enhance the utility of both existing and new ultrasound systems and extend the use of ultrasound technology to circumstances that either require the use of expensive CT or MRI imaging systems or where imaging is not practical using existing technology. To demonstrate the capabilities of our TAEUS platform, we have conducted various internal ex-vivo laboratory experiments and have also conducted limited internal in-vivo large animal studies. In our ex-vivo and in-vivo testing, we have demonstrated that the TAEUS platform has the following capabilities and potential clinical applications:

- **Tissue Composition:** Our TAEUS technology enables ultrasound to distinguish fat from lean tissue. This capability would enable the use of TAEUS-enhanced ultrasound for the early identification, staging and monitoring of NAFLD, a precursor to non-alcoholic steatohepatitis (“NASH”), liver fibrosis, cirrhosis and liver cancer.
- **Temperature Monitoring:** Our TAEUS technology enables traditional ultrasound to visualize changes in tissue temperature, in real time. This capability would enable the use of TAEUS-enhanced ultrasound to guide thermoablative therapy, which uses heat or cold to remove tissue, such as in the treatment of cardiac atrial fibrillation, or removal of cancerous liver and kidney lesions, with greater accuracy.
- **Vascular Imaging:** Our TAEUS technology enables ultrasound to view blood vessels from any angle, using only a saline solution contrasting agent, unlike Doppler ultrasound, which requires precise viewing angles. This capability would enable the use of TAEUS-enhanced ultrasound to easily identify arterial plaque or malformed vessels.
- **Tissue Perfusion:** Our TAEUS technology enables ultrasound to image blood flow at the capillary level in a region, organ or tissue. This capability could be used to assist physicians in characterizing microvasculature fluid flows symptomatic of damaged tissue, such as internal bleeding from trauma, or diseased tissue, such as certain cancers.

In addition, to further test the capability of our TAEUS platform to distinguish tissue composition in conjunction with an NAFLD application, we have engaged the Centre for Imaging Technology Commercialization (“CIMTEC”), a contract research organization, to initiate human studies.

Because of the large number of traditional ultrasound systems currently in global use, we are first developing our TAEUS technology for sale as an aftermarket accessory that works with existing ultrasound systems. Because our TAEUS technology is designed to enhance the utility of, not replace, conventional ultrasound, we believe healthcare providers will be able to increase the utilization of, and generate new revenue from, their existing ultrasound systems once we obtain required regulatory approval for specific applications. Based on our design work and our understanding of the ultrasound accessory market, we intend to price our initial NAFLD TAEUS application at a price point approximating \$40,000 to \$50,000, which should enable purchasers to recoup their investment in less than one year by performing a relatively small number of additional ultrasound procedures. We further believe that clinicians will be attracted to our technology because it will enable them to perform more procedures with existing ultrasound equipment, thereby retaining more imaging patients in their clinics rather than referring patients out to a regional medical center for a CT or MRI scan.

ENDRA’s first clinical product will be designed to interface with a conventional ultrasound scanner, utilizing the scanner’s B-mode imaging to guide the selected region for assessment of liver fat content. The following sub-systems will comprise ENDRA’s first generation product.

Radio Frequency (RF) Source and Computer:

The RF source consists of a low power waveform generator and an amplifier. Together, these components provide the characteristic pulses required to excite thermoacoustic signals in tissue. The computer provides processing capability to both utilize the conventional ultrasound data for navigation to the measurement site of interest, and the calculations required to convert digitized thermoacoustic signals to measurements of fat in liver tissue. The entire sub-system will reside in a single enclosure, on wheels, and sit adjacent to the ultrasound imaging system.

Specialized Transducer:

A single channel ‘receive only’ ultrasound transducer is specifically designed and optimized for thermoacoustic imaging. The transducer sub-system will detect thermoacoustic signals excited by the RF source within the liver. The transducer assembly includes electronics for signal amplification, digitization, and signal processing. The specialized transducer will attach to the conventional ultrasound probe used for liver imaging.

RF Applicator:

The RF applicator transmits pulses of energy, provided by the RF source, into tissue. The applicator is positioned in proximity to the target region for measurement.

A second generation product is expected to provide two dimensional imaging with a transducer composed of multiple receive elements. The RF source and applicator will be similar to those in the first generation product but the multi-element transducer will allow for multiple applications including: reading tissue composition, temperature, vascular flow, tissue perfusion, and other potential applications. Ultimately, we expect our technology will be incorporated into conventional ultrasound systems and our business model will transition from producing stand-alone systems to licensing our technology, IP and specialized components to ultrasound OEMs. Existing ultrasound equipment already includes power supplies, computation, high speed electronics, and ultrasound transducers, which may be leveraged by our thermoacoustic imaging applications. The RF source and applicator are the principal hardware components that will be added to OEM ultrasound systems for the OEM fully integrated form of our product.

We are following a model that mirrors the approach used by companies in the past to introduce new ultrasound imaging capabilities to existing conventional ultrasound scanners. Color Doppler, elastography, 3-D imaging, and high channel count systems were all introduced by new companies (not already involved in conventional ultrasound imaging). Historically, ultrasound imaging has grown through the introduction of unique technology and capabilities that expanded the applications and use of clinical ultrasound in a form that often added separate hardware to existing ultrasound systems. Ultimately, as these new technologies gained acceptance in the marketplace they were incorporated into OEM-designed and built systems that were sold by the leading ultrasound imaging vendors.

Sales of ultrasound diagnostic equipment were approximately \$4.4 billion globally in 2017 and are expected to grow at approximately 4.4% annually. There are an estimated 925,000 installed systems generating over 400 million annual diagnostic ultrasound procedures globally. Additionally, an estimated 30,000 to 50,000 new and replacement systems are sold into the market each year. These numbers include both portable and cart-based ultrasound systems, and cover all types of diagnostic ultrasound procedures, including systems intended for cardiology, prenatal and abdominal use. We do not intend to address low-cost, portable ultrasound systems and systems focused on applications, such as prenatal care, where we believe our TAEUS technology will not substantially impact patient care. Accordingly, we define our addressable market for one or more of our TAEUS applications at approximately 338,000 cart-based ultrasound systems currently in use throughout the world.

Potential Clinical Applications for our TAEUS Technology

Early Diagnosis and Monitoring of Non-Alcoholic Fatty Liver Disease, or NAFLD

Our first TAEUS platform application will focus on quantifying fat in the liver and stage progression of NAFLD which, untreated, can progress to Non-Alcoholic Steato-Hepatitis, or NASH, cirrhosis and liver cancer. In 2011, over 1.4 billion people were affected by NAFLD/NASH. The World Gastroenterology Organisation considers NAFLD/NASH a global pandemic affecting rich and poor countries alike. Obesity, hepatitis, and diabetes are leading contributors to the development of NAFLD.

Untreated, an estimated 30% of NAFLD cases progress to NASH, a condition in which liver fat causes inflammation and decreased liver function, resulting in fatigue, weight loss, muscle pain and abdominal pain.

Approximately 25% of NASH cases progress to liver fibrosis, in which liver inflammation causes scar tissue which eventually prevents the liver from functioning properly. The scar tissue blocks the flow of blood through the liver and slows the processing of nutrients, hormones, drugs, and naturally produced toxins. It also slows the production of proteins and other substances made by the liver. Once a patient develops cirrhosis of the liver, the only life-saving therapy is a liver transplant. Additionally, cirrhosis patients may develop liver cancer. In 2015, the World Health Organization estimated that liver cancer kills 745,000 people annually. Because of the increased incidence of obesity, hepatitis and diabetes throughout the world, NAFLD has become the most common chronic liver disease and an important cause of cirrhosis and liver cancer worldwide.

Despite the increased incidence of NAFLD and its role in the development of NASH, cirrhosis and liver cancer, we believe that no low-cost, accurate and safe method exists for measuring fat in the liver. Current liver enzyme blood tests are indicative, but cannot reliably confirm early stage NAFLD or NASH, and liver enzyme levels are normal in a large percentage of patients with NAFLD. Existing ultrasound technology can only measure fat qualitatively in the liver at moderate to severe levels, typically greater than 30% liver fat, and ultrasound has low accuracy when used on obese patients. While early stage NAFLD and NASH can be confirmed by an MRI scan, an MRI scan is expensive, and MRI systems are not widely available or practical for many patients. A surgical biopsy can be used to confirm NAFLD and NASH, but is also expensive, involves a painful procedure and exposes patients to the risk of infection. Furthermore, MRIs and surgical biopsies are impractical for repeated screening and monitoring of liver disease. We believe these limitations negatively impact the diagnosis and treatment of patients with NAFLD.

Patients diagnosed with NAFLD and related liver diseases are typically treated with therapies such as statins, insulin sensitizers and other compounds and are encouraged to adopt lifestyle changes to improve their overall health.

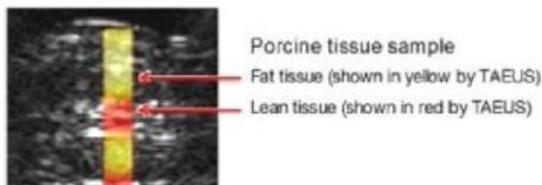
A significant number of pharmaceutical compounds targeting liver disease are in development by companies such as Bristol-Myers Squibb Company, Intercept Pharmaceuticals, Inc., Gilead Sciences, Inc., Genfit SA, Conatus Pharmaceuticals Inc., Allergan plc and Immuron Limited.

Billions of dollars are spent annually on the diagnosis and treatment of NAFLD and related liver diseases. In the United States alone, the median Medicare inpatient charge per NAFLD patient is estimated to be \$36,000 and the total annual direct medical costs for NAFLD are estimated to be \$103 billion. Identification and staging of NAFLD is central to determining the course of treatment.

In addition, patients receiving treatment for NAFLD-spectrum liver diseases must continue to be monitored to assess disease progression and the efficacy of treatment. Because of the high cost and limited global availability, CT and MRI technology is not typically used for this function.

We believe our TAEUS technology will enable primary care physicians, radiologists and hepatologists to diagnose NAFLD earlier and monitor patients with NAFLD-spectrum liver diseases more accurately and cost-effectively than is possible with existing technology.

Image below: Depiction of ex-vivo TAEUS tissue composition analysis overlaid on traditional ultrasound image. First version of TAEUS is expected to assess fat in liver only.



Temperature Monitoring of Thermoablative Surgery

We also intend to develop a TAEUS platform application to guide thermal ablation surgery, such as in the treatment of cardiac atrial fibrillation, chronic pain and lesions of the liver, thyroid, kidneys and other soft tissues. We plan to target clinical users of thermoablative technology, including interventional radiologists, cardiologists, gynecologists and surgical oncologists.

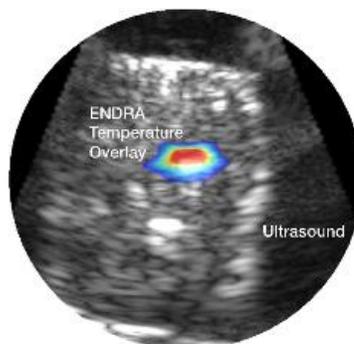
Thermoablation involves the use of heat or cold to remove malfunctioning or diseased tissue in surgical oncology, cardiology, neurology, gynecology, and urology applications. Thermoablative technologies include RF, microwave, laser and cryogenic ablation. The worldwide market for RF surgical ablation procedures alone was estimated in 2015 to be \$3.7 billion per annum, generating over 5 million annual RF ablation procedures and growing at approximately 18% annually. We believe that the growth of this market is driven primarily by the aging global population requiring more cardiac and cancer procedures, as well as the relative ease-of-use and low cost of thermoablative technologies when compared to open surgery.

However, RF and other thermoablative surgery technologies pose risks, including under-treatment of diseased tissue and unintended thermal damage to areas outside the treatment area. For example, it has been reported that patients receiving RF ablation of liver tumors have experienced thermal injury to the diaphragm, gallbladder, bile ducts and gastrointestinal tract, some of which have resulted in patient deaths.

Clinicians must rely on printed manufacturer guidelines to plan procedures using thermal ablation technologies or, when available, monitor tissue temperature changes in real-time with MRI imaging or surgical temperature probes. We believe these existing methods either lack real-time precision or are impractical due to cost, poor availability and other factors.

We believe that the ability to visualize changes in tissue temperature in real time could potentially enhance the effectiveness and safety of thermoablation therapies and that our TAEUS technology platform combined with traditional ultrasound has the potential to guide thermoablation surgery more cost-effectively and more accurately than existing methods.

Image below: Depiction of ex-vivo TAEUS tissue temperature analysis overlaid on traditional ultrasound image.



Vascular Imaging

We believe that our TAEUS technology can be used to image blood vessels and distinguish them from the surrounding tissue. In addition to our NAFLD and thermoablation applications, we intend to develop a cardiovascular application based on our TAEUS technology that, with the use of a standard saline contrast agent, can enable existing ultrasound systems to perform a number of cardiovascular diagnostic functions, such as identifying arterial plaque or blocked or malformed vessels, as well as safely guiding biopsies away from vital vasculature.

Conventional ultrasound imaging systems use Doppler imaging in a variety of vascular applications. Doppler ultrasound, which images the velocity of blood, is effective in larger vessels and regions where blood velocity is high. However, Doppler ultrasound is not sufficiently sensitive for use in very small vessels or in vascular imaging applications where blood velocities are very low. For these applications, contrast enhanced CT and MRI angiography is used which requires the patient to be injected with a contrast agent, iodinated compounds and gadolinium, respectively. Contrast-enhanced CT and MRI scans both require referral for examination after initial screening with ultrasound and carry risks associated with their respective contrast agents. We believe that our TAEUS platform application has the potential to offer the advantages of CT and MR contrast enhanced imaging at the point of care using only a safe electrolyte solution as the contrast agent.

Tissue Perfusion or “Leakiness”

We believe that our TAEUS technology can be used to image tissue perfusion, or the absorption of fluids into an organ or tissue. We intend to develop an application for our TAEUS platform that would enable ultrasound detection of microvasculature fluid flows symptomatic of tissue compromised by trauma or disease.

When a person’s body is affected by disease or trauma, blood and other fluids may leak from damaged tissues in subtle ways. Traditional ultrasound cannot effectively image these disruptions in microvascular permeability, but we believe ultrasound combined with our TAEUS technology can.

We believe that using our TAEUS technology physicians will be able to quickly and clearly see tissue compromised by disease, such as cancer, or trauma, especially with the use of a standard saline contrast agent, when CT or MRI is not readily available.

Collaboration with GE Healthcare

On April 22, 2016, we entered into a Collaborative Research Agreement with General Electric Company, acting through its GE Healthcare business unit and the GE Global Research Center, or GE Healthcare. Under the terms of the agreement, GE Healthcare has agreed to assist us in our efforts to commercialize our TAEUS technology for use in a fatty liver application by, among other things, providing equipment and technical advice, and facilitating introductions to GE Healthcare clinical ultrasound customers. In return for this assistance, we have agreed to afford GE Healthcare certain rights of first offer with respect to manufacturing and licensing rights for the target application. More specifically, we have agreed that, prior to commercially releasing our TAEUS technology for a fatty liver application, we will offer to negotiate an exclusive ultrasound manufacturer relationship with GE Healthcare for a period of at least one year of commercial sales. The commercial sales would involve, within our sole discretion, either our company commercially selling GE Healthcare ultrasound systems as the exclusive ultrasound system with their TAEUS fatty liver application embedded, or GE Healthcare being the exclusive ultrasound manufacturer to sell ultrasound systems with the TAEUS fatty liver application technology embedded.

The agreement with GE Healthcare does not prevent us from selling our TAEUS fatty liver application technology to distributors or directly to non-manufacturer purchasers.

Additionally, the agreement provides that prior to offering to license any of our TAEUS fatty liver application intellectual property to a third party, we will first offer to negotiate to license our TAEUS fatty liver application intellectual property to GE Healthcare.

Finally, we agreed that prior to selling any equity interests in our company to a healthcare device manufacturer, we will first offer to negotiate in good faith to sell such equity interests to GE Healthcare.

The term of the agreement has been extended to January 2020, but the agreement is subject to termination by either party upon not less than 60 days' notice.

Our Nexus 128 System for Laboratory Research

Since 2010 we have marketed our Nexus 128 system to address the imaging needs of researchers studying disease models in pre-clinical applications. The Nexus 128 uses near-infrared light combined with ultrasound to generate 3D images of tumors in laboratory mice. We believe the Nexus 128 is the only commercially available fully 3D thermoacoustic imaging system.

Sales of the Nexus 128 system were approximately \$500,000 in 2016 and \$287,000 in 2017. Our Nexus 128 system is used in a number of leading global academic research centers, including Stanford University, The University of Michigan, Shanghai Jiao Tong University, and Purdue University.

While our Nexus 128 system is suited for small animal research, the near-infrared light energy used in our Nexus 128 system only penetrates tissues up to 3cm, limiting its utility beyond shallow-depth human dermatological or breast applications. Additionally, blood-filled organs, such as the liver, absorb most of the near-infrared light, making it difficult to generate an accurate image.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws and other agreements with employees and third parties to establish and protect our proprietary intellectual property rights. We require our officers, employees and consultants to enter into standard agreements containing provisions requiring confidentiality of proprietary information and assignment to us of all inventions made during the course of their employment or consulting relationship. We also enter into nondisclosure agreements with our commercial counterparties and limit access to, and distribution of, our proprietary information.

We are committed to developing and protecting our intellectual property and, where appropriate, filing patent applications to protect our technology. Our issued and pending patents claims are directed at the following areas related to our technology:

- Methods to induce and enhance thermoacoustic signal generation;
- System configurations, devices and novel hardware for transmission of RF pulses into tissue and detection of acoustic signals;
- Methods for integrating our devices with existing conventional ultrasound systems; and
- Methods and algorithms for signal processing, image formation and analysis.

We currently maintain a patent portfolio consisting of two US and two foreign issued patents, nine patent applications pending in the United States and ten patent applications pending in foreign jurisdictions. These patents and patent applications cover certain innovations relating to contrast-enhanced imaging as well as several aspects of fat imaging and fat quantitation in the liver and other tissues.

In addition, we have in-licensed four U.S. patents, three foreign patents. These patents protect a number of key design attributes that are specific to our Nexus 128 product.

Each of our patents generally has a term of 20 years from its respective priority filing date. Among our issued patents, the first patents are set to expire in 2018 and the last patents expire in 2031.

Sales and Marketing

We currently do not have a sales and marketing team dedicated to our TAEUS clinical applications. In parallel to securing all necessary government marketing approvals, we intend to hire a small internal marketing team to engage and support channel partners and clinical customers. As we have done with our Nexus 128 system, we intend to partner with several geographically-focused independent clinical ultrasound equipment distributors to market and sell our TAEUS applications. We believe that these distributors have existing customer relationships, a strong knowledge of diagnostic imaging technology and the capabilities to support the installation, customer training and post-sale service of capital equipment and software.

We also intend to work with original equipment manufacturers, or OEMs, of ultrasound and thermal ablation equipment to sell our TAEUS applications alongside their own new systems and into their existing installed base systems. We believe that these OEMs will find our applications attractive as they will enable them to generate additional revenue from their installed systems – as they currently do with aftermarket accessory portfolios. We believe our relationship with GE Healthcare will facilitate this strategy.

Based on our design work and our understanding of the ultrasound accessory market, we intend to price our initial NAFLD TAEUS application at a price point approximating one-half of the price of a new cart-based ultrasound system, which should enable purchasers to recoup their investment in less than one year by performing a relatively small number of additional ultrasound procedures.

Some of our TAEUS offerings are expected to be implemented via a hardware platform that can run multiple individual software applications that we will offer TAEUS users for a one-time licensing fee, enabling users to perform more procedures with their existing ultrasound equipment and retaining more patients in their clinics rather than referring them out to a regional imaging medical center for a CT or MRI scan.

We also intend to license our TAEUS technology to OEMs, such as GE Healthcare, for incorporation in their new ultrasound systems.

We currently market our Nexus 128 pre-clinical system domestically in North America through a small internal marketing team and a network of distributors in the United Kingdom, the European Union, Australia, China and Korea. We use our corporate website, sales materials and key industry meetings to drive customer awareness, interest and trial of our products.

Engineering, Design and Manufacturing

Development of TAEUS Device

We have contracted with StarFish Product Engineering, Inc. ("StarFish"), a medical device contract manufacturing company, to commence the productization of our NAFLD TAEUS application. In particular, we have retained StarFish to develop ENDRA's current prototype TAEUS device into a clinical product meeting CE regulatory requirements required for commercial launch. We expect to further engage StarFish to support our application for a CE mark that will enable us to sell the application in the European Union as a Class IIa medical device once a final design for our TAEUS device has been developed and tested, and to lead the preparation of documentation for regulatory approval submission both in the European Union and in the United States. In order to foster collaboration, our Chief Technology Officer regularly visits StarFish's facilities to monitor the TAEUS application manufacturing process.

Additionally, we have also engaged CriTech Research, Inc. ("CriTech"), a firm specializing in medical device software, to develop the software that will support the operation of our TAEUS device.

We believe that our contract manufacturers will either supply necessary components internally or obtain them from third-party sources. At this time, we do not know whether any components are or will be single sourced.

Regulatory Approval Pathway

Each of our TAEUS platform applications will require regulatory approvals before we are able to sell or license the application. Based on certain factors, such as the installed base of ultrasound systems, availability of other imaging technologies, such as CT and MRI, economic strength and applicable regulatory requirements, we intend to seek initial approval of our applications for sale in the European Union, followed by the United States and China.

The first TAEUS application we intend to commercialize is our NAFLD TAEUS application. Our initial target market for this application is the European Union. We believe that our NAFLD TAEUS application will qualify for sale in the European Union as a Class IIa medical device. As a result, we will be required to obtain a CE mark for our NAFLD TAEUS application before we can sell the application in the European Union. To this end, we have contracted with medical device contract engineering firms to perform the commercial product engineering for our NAFLD TAEUS application. Existing regulations would not require us to conduct a clinical trial to obtain a CE mark for this application. Nonetheless, for commercial reasons and to support our CE mark application we have contracted the Centre for Imaging Technology Commercialization, a medical imaging research group, to conduct human studies to demonstrate our NAFLD TAEUS application's ability to distinguish fat from lean tissue.

In 2012, the European Commission proposed a new regulatory scheme that, if implemented, will impose significant additional obligations on medical device companies. Expected changes include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by government accredited groups for some types of medical devices, and tightened and streamlined quality management system assessment procedures. It is anticipated that this new regulatory scheme may be implemented prior to receipt of the CE mark for our NAFLD TAEUS application, but we believe that applicable transition rules should allow us to avoid their application in that case. However, such new rules could impose additional requirements, such as a requirement to conduct clinical trials, on future CE mark applications we make.

After the process of obtaining a CE mark for our NAFLD TAEUS application is complete and if we are able to raise additional capital, we intend to prepare for submission to the U.S. Food and Drug Administration, or the FDA, an application under the Food, Drug and Cosmetic Act, or the FD&C Act, to sell our NAFLD TAEUS application in the U.S. We anticipate that the application, as well as those for our other TAEUS applications, will be submitted for approval under Section 510(k) of the FD&C Act. We expect that our initial FDA clearance will allow us to sell the NAFLD TAEUS application in the U.S. with general imaging claims. However, we will need to obtain additional FDA clearances to be able to make diagnostic claims for fatty tissue content determination. Accordingly, to support our commercialization efforts we expect that, following receipt of our initial FDA clearance, we will submit one or more additional applications to the FDA, each of which will need to include additional clinical trial data, so that following receipt of the necessary clearances we may make those diagnostic claims.

Nexus 128 Product

We assemble our Nexus 128 products from components provided to us by third-party component suppliers and manufacturers. While many of the components are off-the-shelf components available from multiple suppliers, our proprietary receiver array is specially manufactured to our specifications by one manufacturer. To date, we have not experienced any component shortages. We do not have any long-term supply or manufacturing agreements related to our Nexus 128 products and components are obtained on a purchase order basis when required.

Regulation

European Union

The primary regulatory environment in Europe is the European Union, which consists of 28 member states encompassing most of the major countries in Europe. We believe that in the European Union applications incorporating our TAEUS technology will be regulated as Class IIa medical devices by the European Medicines Agency, or EMA, and the European Union Commission. As described above, we expect our applications will receive a CE mark from an appropriate Competent Authority as a result of successful review of one or more submissions prepared by our contract engineering and manufacturer(s), so that such applications can be marketed and distributed within the European Economic Area. Each of our applications will be required to be recertified each year for CE marking, which recertification may require an annual audit. The audit procedure, which will include on-site visits at our facility, and the contract manufacturer's(s') facility(ies), will require us to provide the contract manufacturer(s) with information and documentation concerning our quality management system and all applicable documents, policies, procedures, manuals, and other information.

In the European Union, the manufacturer of medical devices is subject to current Good Manufacturing Practice, or cGMP, as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with cGMP is generally assessed by a Notified Body accredited by a Competent Authority. For a Class IIa device, typically, quality system evaluation is performed by the Notified Body, which also recommends to the relevant Competent Authority for the European community whether a device will receive a CE mark. The Notified Body may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each application, 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 application.

FDA Regulation

Each of our products must be approved or cleared by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our applications are subject to extensive regulation by the FDA under the FD&C Act and/or the Public Health Service Act, as well as by other regulatory bodies. The FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products.

FDA Approval or Clearance of Medical Devices

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

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

We expect all of our products to be classified as Class II medical devices and require FDA authorization prior to marketing by means of a 510(k) clearance.

To request marketing authorization by means of a 510(k) clearance, we must submit a premarket 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 FDA issues a clearance letter finding substantial equivalence. The typical duration to receive a 510(k) approval is approximately nine to twelve months from the date of the initial 510(k) submission, although there is no guarantee that the timing will not be longer.

In the past, the 510(k) pathway for product marketing has required only proof of substantial equivalence in technology for a given indication with a previously cleared device. Recently, there has been a trend of the FDA requiring additional clinical work to prove efficacy in addition to technological equivalence and basic safety. Whether clinical data is provided or not, the FDA may decide to reject the substantial equivalence argument we present. If that happens, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the “de novo” process, which may determine that the new device is of low to moderate risk and that it can be appropriately be regulated as a Class I or II device. If a de novo request is granted, the device may be legally marketed and a new classification is established. If the device is classified as Class II, the device may serve as a predicate for future 510(k) submissions. If the device is not approved through de novo review, then it must go through the standard PMA process for Class III devices.

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, a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then a company must submit, and the FDA must approve, a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with quality system regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, a FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances in which the FDA has not. The FDA must find the information to be satisfactory in order to 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 after 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.

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 FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an investigational device exemption application to the FDA 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 FDA unless the FDA 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 FDA'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 FDA, 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 FDA 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 FDA quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; and
- the Medical Device Reporting regulation, which requires reporting to the FDA 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 regulation promulgated under Section 520 of the FD&C Act. Current good manufacturing practices regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for an approved product must be registered with the FDA and meet current good manufacturing practices requirements to the satisfaction of the FDA pursuant to a pre-PMA approval inspection before the facility can be used. Manufacturers, including third party contract manufacturers, are also subject to periodic inspections by the FDA and other authorities to assess compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA 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.

China Regulation

China’s regulatory approval framework includes nationwide approval based on a showing that the device for which approval is sought has been previously approved in the country of origin. Alternatively, we understand it is also possible to receive approval at the provincial level or to work exclusively with hospitals that do not require such nationwide or provincial approval. We intend to explore these potential paths to regulatory compliance in China.

Other Regulations

We will become 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 EMA or FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from EMA and FDA requirements.

Competition

While we believe that we are the only company developing RF-based thermoacoustic ultrasound products, we will face direct and indirect competition from a number of competitors, many of whom have greater financial, sales and marketing and other resources than we do.

Manufacturers of CT and MRI systems include multi-national corporations such as Royal Philips, Siemens AG and Hitachi, Ltd., many of whom also manufacture and sell ultrasound equipment. In the NAFLD diagnosis market we will compete with makers of surgical biopsy tools, such as Cook Medical and Sterylab S.r.l. In the thermal ablation market, we will compete with manufacturers of surgical temperature probes, such as Medtronic plc and St. Jude Medical, Inc.

Research and Development

Our research and development expenses were \$1,931,075 and \$495,377 for the years ended December 31, 2017 and 2016, respectively.

Employees

As of December 31, 2017, we had 13 employees, all of whom are employed on a full-time basis. 6 full-time employees were engaged in research and development activities, 3 full-time employees were engaged in administrative activities, 2 full-time employees were engaged in product assembly and 2 employees were engaged in marketing activities. None of our employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good.

We also employ technical advisors, on an as-needed basis, to supplement existing staff. We believe that these technical advisors provide us with necessary expertise in clinical ultrasound applications, ultrasound technology, and intellectual property.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all other information contained in this Annual Report, including our financial statements and the related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face, but include the most significant factors currently known by us that make investing in our securities speculative or risky. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, also may become important factors that affect us. If any of the following risks materialize, our business, financial condition and results of operations could be materially harmed. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business

We have a history of operating losses, we may never achieve or maintain profitability, and we will need to raise significant additional capital if we are going to continue as a going concern.

We have limited commercial experience upon which investors may evaluate our prospects. We have only generated limited revenues to date and have a history of losses from operations. As of December 31, 2017, we had an accumulated deficit of approximately \$17.9 million. Our independent registered public accounting firm, in its report on our financial statements for the year ended December 31, 2017, has raised substantial doubt about our ability to continue as a going concern.

We will require additional capital in the near term to continue as a going concern to proceed with the commercialization of our planned TAEUS applications and to meet our growth and profitability targets. We believe that cash on hand at December 31, 2017 and other potential sources of cash, including revenues we may generate from sales of our Nexus 128 system, will be sufficient to fund our current operations into the third quarter of 2018. If we do not raise additional capital in the next several months we will need to significantly slow or pause our development activities until we raise additional funds.

We have expended and expect to continue to expend significant resources on hiring of personnel, payroll and benefits, continued scientific and potential product research and development, potential product testing and pre-clinical and clinical investigations, expenses associated with the development of relationships with strategic partners, intellectual property development and prosecution, marketing and promotion, capital expenditures, working capital, and general and administrative expenses. We also expect to incur costs and expenses related to consulting, laboratory development, and the hiring of scientists and other operational personnel.

We may not be able to secure financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts.

We will need to raise additional capital in order to finance the full commercialization of our first TAEUS application in the European Union and to complete the development of any other TAEUS application through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives.

To date, we have financed our operations primarily through the net proceeds from the issuance of securities, including our initial public offering, as well as sales of our Nexus 128 system. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. Therefore, we will require additional capital in order to: (i) continue to conduct research and development activities; (ii) conduct clinical studies; (iii) fund the costs of seeking regulatory approval of TAEUS applications; (iv) expand our sales and marketing infrastructure; (v) acquire complementary business technology or products; and (vi) respond to business opportunities, challenges, increased regulatory obligations or unforeseen circumstances. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs, timing and outcomes of regulatory reviews associated with our future products, including TAEUS applications;
- the costs and expenses of expanding our sales and marketing infrastructure;
- the costs and timing of developing variations of our TAEUS applications and, if necessary, obtaining regulatory clearance of such variations;
- the degree of success we experience in commercializing our products, particularly our TAEUS applications;
- the extent to which our TAEUS applications are adopted by hospitals for use by primary care physicians, hepatologists, radiologists and oncologists for diagnosis of fatty liver disease and the thermal ablation of lesions;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent and scope of our general and administrative expenses;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals, including the potential that the FDA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the amount of sales and other revenues from technologies and products that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party reimbursement;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;

- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other products;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities; and
- the time and cost necessary to respond to technological and market developments.

We may raise funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we raise additional funds through issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our Company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or products or to grant licenses on terms that may not be favorable to us and our collaborators and strategic partners may not perform as expected.

General market conditions or the market price of our common stock may not support capital raising transactions such as a public or private offering of our common stock or other securities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, results of operation and financial condition, including the possibility that a lack of funds could cause our business to fail and liquidate with little or no return to investors.

Our efforts may never result in the successful development of commercial applications based on our TAEUS technology.

Due to the limited tissue penetration capability of light-based thermoacoustic technology, we believe that there is a limited clinical market for our current Nexus 128 product, which is focused on laboratory specimen analysis. As a result, we are currently focused on the development of products based on our TAEUS technology.

Our TAEUS technology is still in development and we do not have any applications for our TAEUS technology approved for sale. Applications for our TAEUS technology may never be approved, become commercially viable or generate significant revenue. Our ability to generate significant revenues and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive required regulatory approvals for our TAEUS applications and find customers who will purchase our future products or strategic partners that will incorporate our technology into their products. Even if we develop commercially viable applications for our TAEUS technology, which may include licensing, we may never recover our research and development expenses and we may never be able to produce material revenues or operate on a profitable basis.

Our research and development efforts remain subject to all of the risks associated with the development of new products based on emerging technologies, including, without limitation, unanticipated technical or other problems, the inability to develop a product that may be sold at an acceptable price point and the possible insufficiency of funds needed in order to complete development of these products. Technical problems may result in delays and cause us to incur additional expenses that would increase our losses. If we cannot complete, or if we experience significant delays in developing applications based on, our TAEUS technology, particularly after incurring significant expenditures, our business may fail.

Our success is substantially dependent on the success of applications for our TAEUS platform.

To date we have generated only limited sales of our existing Nexus 128 product and our ability to generate meaningful revenues in the future will depend on the successful development and commercialization of our TAEUS platform applications. The commercial success of our TAEUS platform applications and our ability to generate revenues will depend on many factors, including the following:

- our successful development of applications for our TAEUS technology, such as those we intend to pursue for the diagnosis of Non-Alcohol Fatty Liver Disease (“NAFLD”) and the monitoring of thermal ablation surgery, and the acceptance in the marketplace by physicians and patients of such applications;
- the successful design and manufacturing of a device or devices which enable the use of our TAEUS technology by physicians on their patients;
- receipt of necessary regulatory approvals;
- sufficient coverage or reimbursement by third-party payors;
- our ability to successfully market our products;
- our ability to demonstrate that our TAEUS applications have advantages over competing products and procedures;
- the amount and nature of competition from competing or alternative imaging products; and
- our ability to establish and maintain commercial manufacturing, distribution and sales force capabilities.

Our TAEUS platform applications may not achieve adequate market acceptance by the physicians, patients, third-party payors and others in the medical community.

Even if any of our TAEUS applications receives regulatory approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our TAEUS applications do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from sales. The degree of market acceptance of products based on our TAEUS platform will depend on a number of factors, including:

- potential or perceived advantages or disadvantages compared to alternative products;
- pricing relative to competitive products and availability of third-party coverage or reimbursement;
- the timing of bringing our product to market as compared to possible other new entrants to the market;
- our ability to effectively raise market awareness and explain product benefits and whether we have resources sufficient to do so;
- relative convenience, dependability and ease of administration; and
- willingness of the target patient population to try new products and of physicians to utilize such products.

Our revenues will be adversely affected if, due to these or other factors, the products we are able to commercialize do not gain significant market acceptance.

We may not remain commercially viable if there is an inadequate level of reimbursement by governmental programs and other third-party payors.

Medical imaging products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payors, including governmental programs (e.g., Medicare and Medicaid in the United States), private insurance plans and managed care programs, for the services provided to their patients.

Third-party payors and governments may approve or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement decisions by payors for these services are based on a wide range of methodologies that may reflect the services' assessed resource costs, clinical outcomes and economic value. These reimbursement methodologies and decisions confer different, and sometimes conflicting, levels of financial risk and incentives to healthcare providers and patients, and these methodologies and decisions are subject to frequent refinements. Third-party payors are also increasingly adjusting reimbursement rates, often downwards, indirectly challenging the prices charged for medical products and services. There can be no assurance that our products will be covered by third-party payors, that adequate reimbursement will be available or, even if payment is available, that third-party payors' coverage policies will not adversely affect our ability to sell our products profitably.

We have limited data regarding the efficacy of our TAEUS platform applications. If any of our applications that receive regulatory approval do not perform in accordance with our expectations, we are unlikely to successfully commercialize our applications.

Since our success depends in large part on the medical and third-party payors community's acceptance of our TAEUS applications, even if we receive regulatory approval for our applications, we believe that we will need to obtain additional clinical data from users of our applications to persuade medical professions to use our applications. We may also be required to conduct post-approval clinical testing to obtain such additional data. Clinical testing is expensive, can take a significant amount of time to complete and can have uncertain outcomes. We have not yet received the results of clinical studies relating to our TAEUS applications, including human studies to be conducted by the Centre for Imaging Technology Commercialization ("CIMTEC") pursuant to a service agreement, and there can be no assurance that the results of any such studies will be positive. Negative results of these clinical studies could have a material, adverse impact on our business.

Our limited commercial experience makes it difficult to evaluate our business, predict our future results or forecast our financial performance and growth.

We were incorporated in 2007 and began commercializing our initial pre-clinical Nexus 128 product in 2010. No application based on our TAEUS technology has been approved for commercialization. This limited commercial experience makes it difficult to evaluate our business, predict our future results or forecast our financial performance and growth. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

We have formed, and may in the future form or seek, strategic alliances and collaborations or enter into licensing arrangements, and we may not realize the benefits of such alliances, collaborations or licensing arrangements.

On April 22, 2016, we entered into a Collaborative Research Agreement with GE Healthcare under which GE Healthcare has agreed to support our efforts to commercialize our TAEUS technology for use in an NAFLD application by, among other things, providing equipment and technical advice, and facilitating introductions to GE Healthcare clinical ultrasound customers. This agreement does not commit GE Healthcare to a long-term relationship and it may disengage with us at any time. This agreement has a term lasting until January 22, 2020 and is subject to termination by either party upon not less than 60 days' notice. See the section of this Annual Report titled "Collaboration with GE Healthcare" under "Item 1. Business" for further description of this agreement.

We intend in the future to form or seek additional strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our technologies and applications.

Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, restrict our ability to collaborate with other third parties or otherwise disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. If we license technologies or applications, we may not be able to realize the intended benefit of such transactions. Further, strategic alliances and collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our technologies and applications or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon the development of an application, repeat or conduct new clinical trials, or require a new formulation of an application for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our applications and technologies;
- a collaborator with marketing and distribution rights to one or more applications may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our technologies and applications, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable applications or technologies; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our applications or technologies, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our applications could delay the development and commercialization of our technologies and applications in certain geographies or for certain applications, which would harm our business prospects, financial condition and results of operations.

We have limited resources and will depend on third parties to design and manufacture, and seek regulatory approval of, our TAEUS applications. If any third party fails to successfully design, manufacture or obtain regulatory approval of TAEUS applications, our business will be materially harmed.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to design or manufacture our TAEUS applications. To support our design and manufacturing efforts, we have contracted StarFish Product Engineering, Inc., a medical device contract manufacturing company, and CriTech Research, Inc., a firm specializing in medical device software development, rather than design or manufacture our TAEUS applications ourselves. We have limited control over the efforts and resources that these and any other third-party original equipment manufacturers ("OEMs") will devote to developing and manufacturing our TAEUS applications and their capabilities to serve our needs, including quality control, quality assurance and qualified personnel. In addition, we currently expect to depend on OEMs to acquire CE marks for the device or devices that they develop and manufacture which are necessary to permit marketing of those devices in the European Union followed by corresponding FDA approval.

An OEM may not be able to successfully design and manufacture the products it develops based on our TAEUS technology, may not devote sufficient time and resources to support these efforts or may fail in gaining the required regulatory approvals of our TAEUS applications. The failure by an OEM to perform in accordance with our expectations would substantially harm the value of our TAEUS technology, brand and business.

We will need to develop marketing and distribution capabilities both internally and through our relationships with third parties in order to sell any of our TAEUS products receiving regulatory approval. If we experience problems in developing these capabilities, our ability to sell our products could be limited.

We have limited experience selling our products and will need to develop marketing, sales and distribution capabilities in order to sell any of our TAEUS applications that receive the necessary regulatory approval. We have limited experience managing a sales force and customer support operations and may be unable to attract, retain and manage the collaborative manufacturing and distribution arrangements or the specialized workforce necessary to successfully commercialize our products. In addition, our sales and marketing organization must effectively explain the uses and benefits of our products as compared to alternatives in order to promote market acceptance and demand for our products. Developing these functions is time consuming and expensive and our efforts may not be successful.

We intend to partner with others to assist us with some or all of these functions. However, we may be unable to find appropriate third parties with which to enter into these arrangements and any such third parties may not perform as expected.

Furthermore, third-party distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our TAEUS applications and grow or maintain product sales. If these distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products. In addition, disagreements with our distributors or non-performance by these third parties could lead to costly and time-consuming litigation or arbitration and disrupt distribution channels for a period of time and require us to re-establish a distribution channel.

If we are unable to manage the growth of our business, our future revenues and operating results may be harmed.

Because of our small size, growth in accordance with our business plan, if achieved, will place a significant strain on our financial, technical, operational and management resources. As we expand our activities, there will be additional demands on these resources. The failure to continually upgrade our technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties, including issues relating to our research and development activities and retention of experienced scientists, managers and technicians, could have a material adverse effect on our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to implement these actions in a timely manner, our results may be adversely affected.

Competition in the medical imaging market is intense and we may be unable to successfully compete.

In general, competition in the medical imaging market is very significant and characterized by extensive research and development and rapid technological change. Competitors in this market include very large companies with significantly greater resources than we have. To successfully compete in this market we will need to develop TAEUS applications that offer significant advantages over alternative imaging products and procedures for such applications.

While we believe the technology behind our TAEUS platform is unique in the industry, developments by other medical imaging companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive. Alternative medical imaging devices may be more accepted or cost-effective than our products. Competition from these companies for employees with experience in the medical imaging industry could result in higher turnover of our employees. If we are unable to respond to these competitive pressures, we could experience delayed or reduced market acceptance of our products, higher expenses and lower revenue. If we are unable to compete effectively with current or new entrants to these markets, we will be unable to generate sufficient revenue to maintain our business.

Changes in the healthcare industry could result in a reduction in the size of the market for our products or may require us to decrease the selling price for our products, either of which could have a negative impact on our financial performance.

Trends toward managed care, healthcare cost containment, and other changes in government and private sector initiatives in Europe, the United States and China are placing increased emphasis on lowering the cost of medical services, which could adversely affect the demand for or the prices of our products. For example:

- major third-party payors of hospital and non-hospital based healthcare services could revise their payment methodologies and impose stricter standards for reimbursement of imaging procedures charges and/or a lower or more bundled reimbursement;
- there has been a consolidation among healthcare facilities and purchasers of medical devices who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;
- there is economic pressure to contain healthcare costs in markets throughout the world; and
- there are proposed and existing laws and regulations in international and domestic markets regulating pricing and profitability of companies in the healthcare industry.

These trends could lead to pressure to reduce prices for our products and could cause a decrease in the demand for our products in any given market that could adversely affect our revenue and profitability, which could harm our business.

We intend to market our TAEUS applications, if approved, globally, in which case we will be subject to the risks of doing business outside of the United States.

Because we intend to market our TAEUS applications, if approved, globally, our business may be subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain countries;
- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- effects of applicable local tax structures and potentially adverse tax consequences; and
- significant adverse changes in currency exchange rates.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success largely depends upon the continued services of our executive management team and key employees. The loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Our executive management team has significant experience and knowledge of medical devices and ultrasound systems, and the loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend significant time and money in the pursuit of replacements, which may result in a delay in the implementation of our business plan and plan of operations. We can give no assurance that we could find satisfactory replacements for these individuals on terms that would not be unduly expensive or burdensome to us.

To execute our growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices. In addition, we will need to identify and hire sales executives and competition for commercial and marketing talent is significant. We may experience difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the U.S. Food, Drug and Cosmetics Act, or the FD&C Act, and similar laws of other countries, and rules and regulations of the U.S. Food and Drug Administration, or the FDA, and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we establish; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain European, Chinese or FDA approval of any of our products and begin commercializing those products in Europe, China or the United States, respectively, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Misdiagnosis, warranty and other claims, as well as product field actions and regulatory proceedings, initiated against us could increase our costs, delay or reduce our sales and damage our reputation, adversely affecting our financial condition.

Our business exposes us to the risk of malpractice, warranty or product liability claims inherent in the sale and support of medical device products, including those based on claims that the use or failure of one of our products resulted in a misdiagnosis or harm to a patient. Such claims may cause financial loss, damage our reputation by raising questions about our products' safety and efficacy, adversely affect regulatory approvals and interfere with our efforts to market our products. Although to date we have not been involved in any medical malpractice or product liability litigation, we may incur significant liability if such litigation were to occur. We may also face adverse publicity resulting from product field actions or regulatory proceedings brought against us. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability or related claims, we may incur substantial liabilities or be required to limit distribution of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and negative media attention;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize a product at all or for particular applications; and
- a decline in the price of our securities.

Although we currently maintain liability insurance in amounts we believe are commercially reasonable, any liability we incur may exceed our insurance coverage. Our insurance policies may also have various exclusions, and we may be subject to a claim for which we have no coverage. Liability insurance is expensive and may cease to be available on acceptable terms, if at all. A malpractice, warranty, product liability or other claim or product field action not covered by our insurance or exceeding our coverage could significantly impair our financial condition. In addition, a product field action or a liability claim against us could significantly harm our reputation and make it more difficult to obtain the funding and commercial relationships necessary to maintain our business.

Our internal computer systems, or those used by third-party manufacturers or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future manufacturers and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs and our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products could be delayed.

The United Kingdom's vote to leave the European Union will have uncertain effects and could adversely affect us.

On June 23, 2016, the United Kingdom held a referendum in which a majority of voters voted to exit the European Union ("EU"), commonly referred to as "Brexit", and on March 29, 2017, notified the EU that it intended to exit as provided in Article 50 of the Treaty of Lisbon. The terms of the withdrawal are subject to a negotiation period that could last at least two years from the withdrawal notification date. This will be either accompanied or followed by additional negotiations concerning future terms of the United Kingdom's relationship with the EU including, among other things, the terms of trade between the United Kingdom and the EU. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to EU markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the Sterling and Euro. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replace or replicate. In addition, Brexit may lead other EU member countries to consider referendums regarding their EU membership. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations, financial condition and cash flows.

Risks Related to Intellectual Property and Other Legal Matters

If we are unable to protect our intellectual property, which entails significant expense and resources, then our financial condition, results of operations and the value of our technology and products could be adversely affected.

Much of our value arises out of our proprietary technology and intellectual property for the design, manufacture and use of medical imaging systems, including development of our TAEUS applications. We rely on patent, copyright, trade secret and trademark laws to protect our proprietary technology and limit the ability of others to compete with us using the same or similar technology. Third parties may infringe or misappropriate our intellectual property, which could harm our business.

We currently maintain a patent portfolio consisting of two US and two foreign issued patents, nine patent applications pending in the United States and ten patent applications pending in foreign jurisdictions relating to our technology. In addition, we currently license four US patents and three pending patent applications in the United States and foreign jurisdictions. We or our licensor may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would.

Expenses related to a patent portfolio include periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which a failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Policing unauthorized use of our proprietary rights can be difficult, expensive and time-consuming, and we might be unable to determine the extent of this unauthorized use

Policing unauthorized use of our intellectual property is difficult, costly and time-intensive. We may fail to stop or prevent misappropriation of our technology, particularly in countries where the laws may not protect our proprietary rights to the same extent as do the laws of the United States. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. If we cannot prevent other companies from using our proprietary technology or if our patents are found invalid or otherwise unenforceable, we may be unable to compete effectively against other manufacturers of ultrasound systems, which could decrease our market share. In addition, the breach of a patent licensing agreement by us may result in termination of a patent license.

We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to our patent activities, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff was previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their former employee's therapeutic development activities for us.

We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our TAEUS applications.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Other medical imaging market participants, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our TAEUS applications to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our TAEUS applications or using product names, which would have a significant adverse impact on our business.

Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products or from using product names that are the same or similar to our product names, and our business may be harmed as a result.

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our TAEUS platform, brand and business.

Risks Related to Government Regulation

Failure to comply with laws and regulations could harm our business.

Our business is or in the future may be subject to regulation by various federal, state, local and foreign governmental agencies, including agencies responsible for monitoring and enforcing employment and labor laws, workplace safety, environmental laws, consumer protection laws, anti-bribery laws, import/export controls, securities laws and tax laws and regulations. In certain jurisdictions, these regulatory requirements may be more stringent than those in the United States. Noncompliance with applicable regulations or requirements could subject us to investigations, sanctions, mandatory recalls, enforcement actions, adverse publicity, disgorgement of profits, fines, damages, civil and criminal penalties or injunctions and administrative actions. If any governmental sanctions, fines or penalties are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, operating results and financial condition could be harmed. In addition, responding to any action will likely result in a significant diversion of management's attention and our resources and substantial costs. Enforcement actions and sanctions could further harm our business, operating results and financial condition.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our TAEUS applications, or if clearances or approvals for future applications and indications are delayed or not issued, our commercial operations will be harmed.

The medical devices that we manufacture and market are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, based on the risk level of the device. Governmental regulations specific to medical devices are wide-ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, pre-clinical and clinical testing, labeling, packaging storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

In the European Union, we will be required to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive) and obtain CE mark certification in order to market medical devices. The CE mark is applied following approval from an independent notified body or declaration of conformity. It is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We believe that our TAEUS applications will qualify for sale in the European Union as Class IIa medical devices. Existing regulations do not require clinical trials to obtain CE marks for Class IIa medical devices. However, in 2012 the European Commission proposed a new regulatory scheme that, if implemented, will impose significant additional obligations on medical device companies. Expected changes include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by government accredited groups for some types of medical devices, and tightened and streamlined quality management system assessment procedures. It is anticipated that this new regulatory scheme may be implemented prior to receipt of the CE mark for our NAFLD TAEUS application but we believe that applicable transition rules should allow us to avoid their application in that case. However, such new rules could impose additional requirements, such as a requirement to conduct clinical trials, on future CE mark applications we make.

We are also required to comply with the regulations of each other country where we commercialize products, such as the requirement that we obtain approval from the FDA and the China Food and Drug Administration before we can launch new products in the United States and China, respectively.

International sales of medical devices manufactured in the United States that are not approved by the FDA for use in the United States, or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the United States due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first.

Before a new medical device or a new intended use for an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval, or PMA, from the FDA, unless an exemption applies. The typical duration to receive a 510(k) approval is approximately nine to twelve months from the date of the initial 510(k) submission and the typical duration to receive a 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.

We expect all of our products to be classified as Class II medical devices that may be approved by means of a 510(k) clearance. In the past, the 510(k) pathway for product marketing has required only proof of substantial equivalence in technology for a given indication with a previously cleared device. Recently, there has been a trend of the FDA requiring additional clinical work to prove efficacy in addition to technological equivalence and basic safety. Whether clinical data is provided or not, the FDA may decide to reject the substantial equivalence argument we present. If that happens, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which may determine that the new device is of low to moderate risk and that it can be appropriately regulated as a Class I or II device. Thus, although at this time we do not anticipate that we will be required to do so, it is possible that one or more of our other products may require approval through the 510(K) de novo process or by means of a PMA.

We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Therefore, even if we believe we have successfully developed our TAEUS technology, we may not be permitted to market TAEUS applications in the United States if we do not obtain FDA regulatory clearance to market such applications. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations that require us to report to certain regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publically available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

Our TAEUS applications may require recertification or new regulatory clearances or premarket approvals and we may be required to recall or cease marketing our TAEUS applications until such recertification or clearances are obtained.

Most countries outside of the United States require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

In the United States, material modifications to the intended use or technological characteristics of our TAEUS applications will require new 510(k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval.

We may not be able to obtain recertification or additional 510(k) clearances or premarket approvals for our applications or for modifications to, or additional indications for, our TAEUS technology in a timely fashion, or at all. Delays in obtaining required future governmental approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If foreign regulatory authorities or the FDA require additional approvals, we may be required to recall and to stop selling or marketing our TAEUS applications, which could harm our operating results and require us to redesign our applications. In these circumstances, we may be subject to significant enforcement actions.

If any OEMs fail to comply with the FDA's Quality System Regulations or other regulatory bodies' equivalent regulations, manufacturing operations could be delayed or shut down and the development of our TAEUS platform could suffer.

The manufacturing processes of OEMs are required to comply with the FDA's Quality System Regulations and other regulatory bodies' equivalent regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our TAEUS applications. They may also be subject to similar state requirements and licenses and engage in extensive recordkeeping and reporting and make available their manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If any OEM fails such an inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our products, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, these OEMs may be engaged with other companies to supply and/or manufacture materials or products for such companies, which would expose our OEMs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a third-party manufacturers' facility. If the FDA or a foreign regulatory agency does not approve these facilities for the manufacture of our products, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would impede or delay our ability to develop, obtain regulatory approval for or market our products, if approved. Additionally, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our results of operations to suffer.

Our TAEUS applications may in the future be subject to product recalls that could harm our reputation.

Governmental authorities in Europe, the United States and China have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our TAEUS applications would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would negatively affect the price of our securities.

Healthcare reform measures could hinder or prevent our planned products' commercial success.

There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. In the European Union, although there have not been any recent amendments to the relevant regulatory legislation, there are ongoing discussions regarding amending the current regulatory framework for medical devices. Moreover, because the Medical Devices Directive requires only minimum harmonization in the European Union, member countries may alter their enforcement of the directives or amend their national regulatory rules. We cannot predict what healthcare initiatives, if any, will be implemented by the European Union or E.U. member countries, or the effect any future legislation or regulation will have on us.

In the United States, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposes an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties.

It remains unclear whether changes will be made to the Affordable Care Act, or whether it will be repealed or materially modified. We cannot assure you that the Affordable Care Act, as currently enacted or as amended or discontinued in the future, will not harm our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. Other jurisdictions such as the European Union have similar laws. The regulations that will affect how we operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal and similar foreign healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations may involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. In addition, our research and development and manufacturing operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third part property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Risks Related to Owning Our Securities, Our Financial Results and Our Need for Financing

Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in volatility in the price of our securities.

Our operating results will be affected by numerous factors such as:

- variations in the level of expenses related to our proposed products;
- status of our product development efforts;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;

- intellectual property prosecution and any infringement lawsuits to which we may become a party;
- regulatory developments affecting our products or those of our competitors;
- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, which have not yet been approved for marketing;
- market acceptance of our TAEUS applications;
- the availability of reimbursement for our TAEUS applications;
- our ability to attract new customers and grow our business with existing customers;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, industry and market conditions;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- litigation or other claims against us;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

Any or all of these factors could adversely affect our cash position requiring us to raise additional capital which may be on unfavorable terms and result in substantial dilution. Additionally, the risks surrounding our business, as well as the limited market for our common stock, have resulted, and will likely continue to result, in volatility in the price of our common stock and warrants. Since shares of our common stock and warrants to purchase our common stock were first listed on the Nasdaq Capital Market on June 28, 2017 through December 31, 2017, the intra-day trading prices have fluctuated from a low of \$2.15 to a high of \$5.88 with respect to shares of our common stock and from a low of \$0.28 to a high of \$2.00 with respect to our warrants and may continue to fluctuate significantly in the future.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

There is a limited market for our common stock .

Although our common stock is traded on the Nasdaq Capital Market, the volume of trading has historically been limited. Our average daily trading volume of our shares from June 28, 2017, when our common stock began trading publicly, to December 31, 2017 was approximately 14,954 shares. Thinly traded stock can be more volatile than stock trading in a more active public market. While we have made efforts to increase trading in our stock, we cannot predict the extent to which an active public market for our common stock will develop or be sustained. Therefore, a holder of our common stock who wishes to sell his or her shares may not be able to do so immediately or at an acceptable price.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our securities and trading volume could decline.

The trading market for our securities is influenced by the research and reports that industry or securities 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 or few analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, the price of our securities would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our securities or trading volume to decline.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities may decrease.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2018, provide a management report on our internal control over financial reporting.

Currently, we have material weaknesses in our internal control over financial reporting and, as a result, we may not detect errors on a timely basis and our financial statements may be materially misstated. Specifically, we have insufficient personnel resources within the accounting function to segregate the duties over financial transaction processing and reporting. We are in the process of improving our internal control over financial reporting, which process is time-consuming, costly and complicated. However, we are a small organization with limited management resources. In addition to serving as our Chief Financial Officer, David Wells provides financial consulting services to several other companies. These other consulting services could prevent Mr. Wells from dedicating sufficient time and attention to us, which could limit our ability to maintain effective internal controls over financial reporting.

Until such time as we are no longer an “emerging growth company” or a smaller reporting company, our auditors will not be required to attest as to our internal control over financial reporting. If we continue to identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective or, if required, if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the stock exchange on which our securities are listed, the Securities and Exchange Commission (the “SEC”) or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We are an “emerging growth company” under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

We will remain an “emerging growth company” for up to five years after the date of our initial public offering, although we will lose that status sooner if our annual revenues exceed \$1 billion, if we issue more than \$1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to further develop our technology and potential products and to cover operating costs. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we will, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.

Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent new investors from influencing significant corporate decisions.

All decisions with respect to the management of the Company are made by our board of directors and our officers, who beneficially own approximately 12.7% of our common stock, as calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In addition, Longboard Capital Advisors, LLC beneficially owns 15.7% of our common stock, as calculated in accordance with Rule 13d-3 promulgated under the Exchange Act. As a result, this stockholder is able to exercise a substantial level of control over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This control could have the effect of delaying or preventing a change of control of the Company or changes in management, which in turn could have a material adverse effect on the market price of the Company’s common stock or prevent stockholders from realizing a premium over the market price for their shares.

We incur significant costs as a result of being a public company that reports to the SEC and our management is required to devote substantial time to meet compliance obligations.

As a public company listed in the United States, we incur significant legal, accounting and other expenses. We are subject to reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. In addition, there are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act Wall Street Reform and Protection Act that contribute to our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Furthermore, 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 people to serve on our board of directors, our board committees or as executive officers.

A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our securities to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of securities intend to sell shares, could reduce the market price of our common stock. We currently have outstanding 3,923,027 shares of common stock. Of these outstanding shares, approximately 1,971,521 are restricted under securities laws or as a result of lock-up agreements but will be able to be resold in the near future.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in dilution of the percentage ownership of our stockholders and could cause the price of our securities to fall.

We expect that significant capital will be needed in the future to continue our planned operations. To the extent we raise capital by issuing common stock, convertible securities or other equity securities, our stockholders may experience substantial dilution, and new investors could gain rights superior to our existing stockholders.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Certain provisions of our Fourth Amended and Restated Certificate of Incorporation (our "Certificate of Incorporation") and Amended and Restated Bylaws (our "Bylaws") and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in 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. The provisions in our Certificate of Incorporation and Bylaws:

- authorize our board of directors to issue preferred stock without stockholder approval and to designate the rights, preferences and privileges of each class; if issued, such preferred stock would increase the number of outstanding shares of our capital stock and could include terms that may deter an acquisition of us;
- limit who may call stockholder meetings;
- do not provide for cumulative voting rights;
- provide that all vacancies in our board of directors may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders must comply with advance notice procedures with respect to stockholder proposals and the nomination of candidates for director;
- provide that stockholders may only amend our Certificate of Incorporation upon a supermajority vote of stockholders; and
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims.

In addition, section 203 of the Delaware General Corporation Law limits our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following any such person's share acquisition. These provisions may have the effect of entrenching our management team and may deprive stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal office is located at 3600 Green Court, Suite 350, Ann Arbor, Michigan 48105-1570. We currently lease approximately 3,950 square feet of office and light industrial/research space under a lease that is due to expire in 2024. The rent is approximately \$7,798 per month, subject to moderate annual increases.

We also maintain an office in London, Ontario, Canada, consisting of two walled offices under a lease that is terminable by either party with 60 days written notice. The rent is approximately \$843 per month, subject to moderate annual increases.

We believe that, with respect to both of our facilities, equivalent suitable space is available at similar rents.

Item 3. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business or financial conditions. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock and warrants have been listed on the Nasdaq Capital Market under the symbols "NDRA" and "NDRAW," respectively, since June 28, 2017 upon the separation of units sold in our initial public offering. Prior to that date, our common stock and warrants traded together as a unit. Our units began trading on the NASDAQ Capital Market under the symbol "NDRAU" on May 9, 2017. Each of our publicly traded warrants is exercisable for a share of our common stock at a price of \$6.25 per share and expires on May 12, 2020.

The following table presents, for the periods indicated, the high and low sales prices for our common stock and warrants

	Common Stock		Warrants	
	High	Low	High	Low
Year Ended December 31, 2017				
Fourth Quarter	\$ 5.88	\$ 2.15	\$ 2.00	\$ 0.36
Third Quarter	\$ 4.00	\$ 2.59	\$ 0.89	\$ 0.26
Second Quarter (from June 28, 2017)	\$ 4.50	\$ 3.80	\$ 1.05	\$ 0.62

During the period from May 9, 2017 (when our units first traded on the Nasdaq Capital Market) through June 27, 2017, the high sales price for our units was \$5.50 and the low sales price was \$4.01.

As of March 15, 2018, there were 1,239 holders of record of our common stock and 259 holders of record of our warrants.

Dividend Policy

We have never paid cash dividends on our securities and we do not anticipate paying any cash dividends on our shares of common stock in the foreseeable future. We intend to retain any future earnings for reinvestment in our business. Any future determination to pay cash dividends will be at the discretion of our board of directors, and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our board of directors deems relevant.

Recent Sales of Unregistered Securities

On November 28, 2017, we issued to a designee of Rick Rutkowski, as compensation for consulting services, a warrant exercisable for 20,000 shares of our common stock at an exercise price of \$4.49 per share, which warrant expires on November 28, 2020.

In connection with the issuances of the foregoing securities, the Company relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

Use of Proceeds from Registered Securities

On May 8, 2017, our Registration Statement on Form S-1, as amended (File No. 333-193522), was declared effective by the SEC and, on May 8, 2017, our Registration Statement on Form S-1 (File No. 333-217788) became effective upon filing with the SEC. Each such Registration Statement was filed in connection with our initial public offering, pursuant to which we sold 1,932,000 units, each consisting of one share of our common stock and a warrant to purchase one share of our common stock, at a price to the public of \$5.00 per unit, which amount includes the full exercise of the underwriters' option to purchase additional units. Each warrant is exercisable for a share of our common stock at a price of \$6.25 per share. The offering closed on May 12, 2017 and the underwriters exercised their over-allotment option as of May 22, 2017, as a result of which we raised net proceeds of approximately \$8.6 million after deducting approximately \$773,000 in underwriting discounts, commissions and expenses and approximately \$297,000 in offering expenses payable by us. National Securities Corporation and Dougherty & Company LLC were the underwriters for the offering. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

The common stock and warrants comprising each unit separated and began trading separately on June 28, 2017. At such time, our units were cancelled and ceased to be listed on the Nasdaq Capital Market.

There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on May 10, 2017.

Item 6. Selected Financial Data

Not required for smaller reporting companies.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the related notes thereto included elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements that are based on our management's current beliefs and assumptions, which statements are subject to substantial risks and uncertainties. Our actual results may differ materially from those expressed or implied by these forward-looking statements as a result of many factors, including those discussed in "Risk Factors" in Item 1A of this Annual Report. Please also see "Cautionary Note Regarding Forward Looking Statements" at the beginning of this Annual Report.

Overview

We have commercialized an enhanced ultrasound technology for the pre-clinical research market and are leveraging that expertise to develop technology for increasing the capabilities of clinical diagnostic ultrasound, to broaden patient access to the safe diagnosis and treatment of a number of significant medical conditions in circumstances where expensive X-ray computed tomography ("CT") and magnetic resonance imaging ("MRI") technology is unavailable or impractical.

Since 2010, we have marketed and sold our Nexus 128 system, which combines light-based thermoacoustics and ultrasound, to address the imaging needs of researchers studying disease models in pre-clinical applications. Sales of the Nexus 128 system were approximately \$500,000 in 2016 and \$287,000 in 2017. Our Nexus 128 system is used in a number of leading global academic research centers, including Stanford University, The University of Michigan, Shanghai Jiao Tong University, and Purdue University. We expect to continue to sell our Nexus 128 system to maintain a base level of revenue, but believe the market potential for our clinical systems is much higher.

Building on our expertise in thermoacoustics, we developed a next-generation technology platform — Thermo Acoustic Enhanced Ultrasound, or TAEUS — which is intended to enhance the capability of clinical ultrasound technology and support the diagnosis and treatment of a number of significant medical conditions that currently require the use of expensive CT or MRI imaging or where imaging is not practical using existing technology.

Unlike the near-infrared light pulses used in our Nexus 128 system, our TAEUS technology uses radio frequency ("RF") pulses to stimulate tissues, using a small fraction of the energy transmitted into the body during an MRI scan. The use of RF energy allows our TAEUS technology to penetrate deep into tissue, enabling the imaging of human anatomy at depths equivalent to those of conventional ultrasound. The RF pulses are absorbed by tissue and converted into ultrasound signals, which are detected by an external ultrasound receiver and a digital acquisition system that is part of the TAEUS system. The detected ultrasound is processed into images using our proprietary algorithms and displayed to complement conventional gray-scale ultrasound images.

We expect that the first-generation TAEUS application will be a standalone ultrasound accessory designed to cost-effectively quantify fat in the liver and stage progression of non-alcoholic fatty liver disease, or ("NAFLD"), which can only be achieved today with impractical surgical biopsies or MRI scans. Subsequent TAEUS offerings are expected to be implemented via a second generation hardware platform that can run multiple clinical software applications that we will offer TAEUS users for a one-time licensing fee – adding ongoing customer value to the TAEUS platform and a growing software revenue stream for our Company.

Each of our TAEUS platform applications will require regulatory approvals before we are able to sell or license the application. Based on certain factors, such as the installed base of ultrasound systems, availability of other imaging technologies, such as CT and MRI, economic strength and applicable regulatory requirements, we intend to seek initial approval of our applications for sale in the European Union, followed by the United States and China.

In April 2016, we entered into a Collaborative Research Agreement with General Electric Company, acting through its GE Healthcare business unit and the GE Global Research Center (collectively, "GE Healthcare"). Under the terms of the agreement, GE Healthcare has agreed to assist us in our efforts to commercialize our TAEUS technology for use in a fatty liver application by, among other things, providing equipment and technical advice, and facilitating introductions to GE Healthcare clinical ultrasound customers. In return for this assistance, we have agreed to afford GE Healthcare certain rights of first offer with respect to manufacturing and licensing rights for the target application. More specifically, we have agreed that, prior to commercially releasing our NAFLD TAEUS application, we will offer to negotiate an exclusive ultrasound manufacturer relationship with GE Healthcare for a period of at least one year of commercial sales. The commercial sales would involve, within our sole discretion, either our Company commercially selling GE Healthcare ultrasound systems as the exclusive ultrasound system with our TAEUS fatty liver application embedded, or GE Healthcare being the exclusive ultrasound manufacturer to sell ultrasound systems with our TAEUS fatty liver application embedded. The agreement is subject to termination by either party upon not less than 60 days' notice. On January 30, 2018, we and GE Healthcare entered into an amendment to our agreement, extending its term by 21 months to January 22, 2020.

On November 2, 2017 we announced that we have partnered with StarFish Medical ("StarFish"), a medical device development and contract manufacturing company, and CriTech Research Inc. ("CriTech"), a U.S. firm specializing in medical device software development, to commence productization of our TAEUS device targeting NAFLD. The agreements call for StarFish and CriTech to provide us with the specialized engineering resources necessary to translate our current prototype TAEUS device into a clinical product meeting CE regulatory requirements required for commercial launch in the European Union followed by FDA submission for the U.S. market.

In November 2017, we also contracted the Centre for Imaging Technology Commercialization (CIMTEC) to initiate human studies with our TAEUS device.

Financial Operations Overview

Revenue

To date our revenue has been generated by the placement and sale of our Nexus 128 system for use in pre-clinical applications.

Cost of Goods Sold

Our cost of goods sold is related to our direct costs associated with the development and shipment of our thermoacoustic imaging systems placed in pre-clinical settings.

Research and Development Expenses

Our research and development expenses primarily include wages, fees and equipment for the development of our TAEUS technology platform and our proposed applications. Additionally, we incur certain costs associated with the protection of our products and inventions through a combination of patents, licenses, applications and disclosures.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of advertising, marketing and consulting expenses and headcount. Currently, our marketing efforts for our pre-clinical business are through distributors in China, the European Union, Australia, Korea and the United Kingdom, our website, and attendance of key industry meetings. In connection with the commercialization of our TAEUS applications, we expect to build a small sales and marketing team to train and support global ultrasound distributors, as well as execute traditional marketing activities such as promotional materials, electronic media and participation in industry conferences.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for our management and personnel, and professional fees, such as accounting, consulting and legal.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Management makes estimates that affect certain accounts including deferred income tax assets, accrued expenses, fair value of equity instruments and reserves for any other commitments or contingencies. Any adjustments applied to estimates are recognized in the period in which such adjustments are determined.

Share-based Compensation

Our 2016 Omnibus Incentive Plan permits the grant of share options and shares to our employees, consultants and non-employee members of our board of directors for up to 1,345,074 shares of common stock. We record share-based compensation in accordance with the provisions of the Share-based Compensation Topic of the FASB Codification. The guidance requires the use of option-pricing models that require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model which uses certain assumptions related to risk-free interest rates, expected volatility, expected life of the common stock options, and future dividends, and the resulting charge is expensed using the straight-line attribution method over the vesting period.

Stock compensation expense recognized during the period is based on the value of share-based awards that were expected to vest during the period adjusted for estimated forfeitures. The estimated fair value of grants of stock options and warrants to non-employees is charged to expense, if applicable, in the financial statements.

Recent Accounting Pronouncements

See Note 2 of the financial statements for a discussion of recently issued accounting standards.

Results of Operations

Years Ended December 31, 2017 and 2016

Revenues

We had revenue of \$351,622 for the year ended December 31, 2017, as compared to \$515,582 for the year ended December 31, 2016, a decrease of \$163,960, or 32%. The revenue was a result of the sale of one of our Nexus 128 laboratory imaging systems and product service fees generated from our installed base of Nexus 128 laboratory imaging systems. The decrease in 2017 over 2016 was due to our limited resources during the first half of 2017 and our decision to focus those resources on developing our TAEUS applications.

Cost of Goods Sold

Cost of goods sold was \$172,782 and \$235,878 for the years ended December 31, 2017 and 2016, respectively, a decrease of \$63,096, or 27%. Cost of goods sold was a result of direct costs associated with the sale of one of our Nexus 128 laboratory imaging systems, and product service materials required for the service of our installed base of Nexus 128 laboratory imaging systems. Gross margin was approximately 51% and 54% for the years ended December 31, 2017 and 2016, respectively. Cost of goods sold decreased as a result of a decrease in units sold. The decrease in gross margin resulted from an increase in the cost of certain parts used to assemble the systems sold.

Research and Development

Research and development expenses were \$1,931,075 for the year ended December 31, 2017, as compared to \$495,377 for the year ended December 31, 2016, an increase of \$1,435,698, or 290%. The costs include primarily wages, fees and equipment for the development of our TAEUS product line. Research and development expenses increased from the same period for the prior year due primarily to increased efforts to develop TAEUS applications with proceeds from our May 2017 initial public offering (the "IPO").

Sales and Marketing

Sales and marketing expenses were \$122,604 for the year ended December 31, 2017, as compared to \$34,130 for the year ended December 31, 2016, an increase of \$88,474, or 259%. The increase was primarily due to the hiring of a full-time sales representative for our Nexus 128 product line. Currently our marketing efforts for our pre-clinical business are through distributors in China, the European Union, Australia and the United Kingdom, our website and attendance of key industry meetings. Our future clinical business will involve hiring and training additional staff to support our sales efforts. As we seek to complete the development and commercialization of our TAEUS applications, we intend to build a small sales and marketing team to train and support global ultrasound distributors, as well as execute traditional marketing activities such as promotional materials, electronic media and participation in industry conferences.

General and Administrative

Our general and administrative expenses for the year ended December 31, 2017 were \$2,751,219, an increase of \$1,209,264, or 78%, compared to \$1,541,956 for the year ended December 31, 2016. General and administrative expenses increased due to an increase in headcount and one-time expenses related to the IPO. Our wage and related expenses for the year ended December 31, 2017 were \$1,286,326, compared to \$705,556 for the year ended December 31, 2016. Wage and related expenses in the year ended December 31, 2017 included \$704,008 of stock compensation expense related to the issuance and vesting of options, compared to \$193,420 of stock compensation expense for the same period in 2016. Our professional fees for the year ended December 31, 2017 were \$1,092,706, compared to \$602,877 for the year ended December 31, 2016. We expect that our general and administrative expenses will increase significantly as a result of our becoming a public company.

Net Loss

As a result of the foregoing, for the year ended December 31, 2017, we recorded a net loss of \$5,376,962 compared to a net loss of \$2,775,368 for the year ended December 31, 2016.

Liquidity and Capital Resources

To date we have generated only limited revenues from sales of our Nexus 128 system. We have funded our operations to date through private and public sales of our securities. As of December 31, 2017, we had approximately \$5.6 million in cash. In May 2017, we completed the IPO, raising net proceeds of approximately \$8.6 million after deducting offering expenses of approximately \$0.8 million in underwriting discounts, commissions and expenses and approximately \$0.3 million in offering expenses payable by the Company.

We believe that cash on hand at December 31, 2017 and other potential sources of cash, including revenues we generate from sales of our Nexus 128 system, will be sufficient to fund our current operations into the third quarter of 2018. If we do not raise additional capital in the next several months we will need to significantly slow or pause our business activities until such time as we are able to raise additional capital. We are currently exploring potential financing options that may be available to us, including additional sales of our common stock. However, we have no commitments to obtain any additional funds, and there can be no assurance such funds will be available on acceptable terms or at all. If we are unable to obtain additional financing in a timely fashion and on terms acceptable to us, our financial condition and results of operations may be materially adversely affected and we may not be able to continue operations or execute our stated commercialization plan.

The financial statements included in this Annual Report have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying financial statements, during the year ended December 31, 2017, we incurred net losses of approximately \$5.4 million, and used cash in operations of approximately \$3.3 million. These and other factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the financial statements. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Operating Activities

During the year ended December 31, 2017, we used \$3,300,914 of cash in operating activities primarily as a result of our net loss of \$5,376,962, offset by amortization of discount of convertible debt of \$711,472, share-based compensation of \$1,002,957, \$61,481 in depreciation and amortization expenses, \$1,480 in imputed interest and net changes in operating assets and liabilities of \$298,659.

During the year ended December 31, 2016, we used \$1,315,623 of cash in operating activities primarily as a result of our net loss of \$2,775,369, offset in part by net changes in operating assets and liabilities of \$254,981, \$64,936 in depreciation and amortization expense, \$230,326 in non-cash stock compensation expense, \$899,976 for the amortization of discount of convertible debt, imputed interest of \$3,704, and \$5,823 for additional warrants issued during the warrant exchange program, pursuant to which we issued warrants to participating warrant holders in exchange for such participants' exercising their then-held warrants.

Investing Activities

During the year ended December 31, 2017, we used \$7,862 in investing activities related to purchase of equipment. There were no investing activities for the year ended December 31, 2016.

Financing Activities

During the year ended December 31, 2017, financing activities provided \$8,590,700 in proceeds from the IPO and \$225,000 in proceeds from convertible notes. We used \$50,000 in repayments of notes payable.

During the year ended December 31, 2016, financing activities provided \$1,441,448, including \$5,000 from common stock issued for cash, \$50,000 in proceeds from notes payable, \$132,000 in proceeds from the issuance of convertible notes, related party, and \$1,254,448 in proceeds from the issuance of convertible notes.

Funding Requirements

We have not completed development of our TAEUS technology platform applications. We expect to continue to incur significant expenses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- advance the engineering design and development of our NAFLD TAEUS application;
- prepare applications required for marketing approval of our NAFLD TAEUS application in the European Union and the United States;
- seek to hire a small internal marketing team to engage and support channel partners and clinical customers for our NAFLD TAEUS application;
- commence marketing of our NAFLD TAEUS application;
- advance development of our other TAEUS applications; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, planned commercialization efforts and our operation as a public company.

It is possible that we will not achieve the progress that we expect because the actual costs and timing of completing the development and regulatory approvals for a new medical device are difficult to predict and are subject to substantial risks and delays. We have no committed external sources of funds. We do not expect that our existing cash will be sufficient for us to complete the commercialization of our NAFLD TAEUS application or to complete the development of any other TAEUS application and we will need to raise substantial additional capital for those purposes. As a result, we will need to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the section of this Annual Report entitled "Risk Factors" and elsewhere in this Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Until we can generate a sufficient amount of revenue from our TAEUS platform applications, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or applications or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Off-Balance Sheet Transactions

At December 31, 2017, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

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ENDRA Life Sciences Inc.

December 31, 2017

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
ENDRA Life Sciences Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ENDRA Life Sciences Inc. and Subsidiary (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for the years ended December 31, 2017 and 2016, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has an accumulated deficit, recurring losses, and expects continuing future losses, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ RBSM LLP

We have served as the Company's auditor since 2015.

Henderson, NV

March 20, 2018

ENDRA Life Sciences Inc.
Consolidated Balance Sheets

Assets	December 31, 2017	December 31, 2016
Assets		
Cash	\$ 5,601,878	\$ 144,953
Accounts receivable	6,850	-
Prepaid expenses	67,496	-
Inventory	191,680	40,105
Other current assets	14,249	10,535
Total Current Assets	5,882,153	195,593
Other Assets		
Fixed assets, net	241,549	295,168
Total Assets	\$ 6,123,702	\$ 490,761
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued liabilities	\$ 848,214	\$ 434,552
Notes payable	-	50,000
Convertible notes payable, related party, net of discount	-	99,804
Convertible notes payable, net of discount	-	800,172
Total Current Liabilities	848,214	1,384,528
Total Liabilities	848,214	1,384,528
Stockholders' Equity (Deficit)		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding	-	-
Common stock, \$0.0001 par value; 50,000,000 shares authorized; 3,923,027 and 723,335 shares issued and outstanding	392	72
Stock payable	-	81,000
Additional paid in capital	23,170,531	11,543,634
Accumulated deficit	(17,895,435)	(12,518,473)
Total Stockholders' Equity (Deficit)	5,275,488	(893,767)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 6,123,702	\$ 490,761

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

ENDRA Life Sciences Inc.
Consolidated Statements of Operations

	Year Ended December 31, 2017	Year Ended December 31, 2016
Revenue	\$ 351,622	\$ 515,582
Cost of Goods Sold	172,782	235,878
Gross Profit	<u>\$ 178,840</u>	<u>\$ 279,704</u>
Operating Expenses		
Research and development	1,931,075	495,377
Sales and marketing	122,604	34,130
General and administrative	2,751,219	1,541,955
Total operating expenses	<u>4,804,898</u>	<u>2,071,461</u>
Operating loss	<u>(4,626,058)</u>	<u>(1,791,758)</u>
Other Expenses		
Loss on warrant exercise	-	(5,823)
Other income (expense)	<u>(750,904)</u>	<u>(977,787)</u>
Total other expenses	<u>(750,904)</u>	<u>(983,610)</u>
Loss from operations before income taxes	<u>(5,376,962)</u>	<u>(2,775,368)</u>
Provision for income taxes	-	-
Net Loss	<u>\$ (5,376,962)</u>	<u>\$ (2,775,368)</u>
Net loss per share – basic and diluted	<u>\$ (1.95)</u>	<u>\$ (3.84)</u>
Weighted average common shares – basic and diluted	<u>2,756,956</u>	<u>723,283</u>

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

ENDRA Life Sciences Inc.
Consolidated Statements of Stockholders' Equity (Deficit)

	<u>Common stock</u>		Additional Paid in Capital	Stock Payable	Accumulated Deficit	Total Stockholders' Equity/(Deficit)
	Shares	Amount				
Balance as of December 31, 2016	<u>723,335</u>	<u>\$ 72</u>	<u>\$11,543,634</u>	<u>\$ 81,000</u>	<u>\$(12,518,473)</u>	<u>\$ (893,767)</u>
IPO shares	1,680,000	168	7,431,332	-	-	7,431,500
Overallotment for IPO	252,000	25	1,159,175	-	-	1,159,200
Note conversion	1,232,859	123	1,950,956	-	-	1,951,079
Common stock issued for services	34,833	4	103,734	(81,000)	-	22,738
Warrants issued for services	-	-	32,709	-	-	32,709
Fair value of vested stock options	-	-	947,511	-	-	947,511
Imputed interest on promissory notes	-	-	1,480	-	-	1,480
Net loss	-	-	-	-	(5,376,962)	(5,376,962)
Balance as of December 31, 2017	<u>3,923,027</u>	<u>\$ 392</u>	<u>\$23,170,531</u>	<u>\$ -</u>	<u>\$(17,895,435)</u>	<u>\$ 5,275,488</u>

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

ENDRA Life Sciences Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31, 2017	Year Ended December 31, 2016
Cash Flows from Operating Activities		
Net loss	\$ (5,376,962)	\$ (2,775,369)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	61,481	64,936
Common stock, options and warrants issued for services	1,002,957	230,326
Addition warrants issued during exchange	-	5,823
Interest on discount of convertible debt	711,472	899,976
Imputed interest on promissory notes	1,480	3,704
Changes in operating assets and liabilities:		
Increase in accounts receivable	(6,850)	-
Increase in prepaid expenses	(67,497)	-
Increase (decrease) in inventory	(151,574)	58,899
Increase in other asset	(3,714)	(2,049)
Increase in accounts payable and accrued liabilities	528,294	198,131
Net cash used in operating activities	<u>(3,300,914)</u>	<u>(1,315,623)</u>
Cash Flows from Investing Activities:		
Purchases of fixed assets	(7,862)	-
Net cash used in investing activities	<u>(7,862)</u>	<u>-</u>
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net	8,590,700	5,000
Proceeds from notes payable	-	50,000
Repayment of notes payable	(50,000)	132,000
Proceeds from convertible notes	225,000	1,254,448
Net cash provided by financing activities	<u>8,765,700</u>	<u>1,441,448</u>
Net Increase in cash	5,456,924	125,825
Cash, beginning of period	144,953	19,128
Cash, end of period	<u>\$ 5,601,878</u>	<u>\$ 144,953</u>
Supplemental disclosures:		
Interest paid	\$ -	\$ -
Income tax paid	\$ -	\$ -
Supplemental disclosures of non-cash Items:		
Discount on convertible notes	\$ 225,000	\$ -
Common shares to be issued for accrued salaries - related parties	\$ -	\$ 60,910
Conversion of convertible notes and accrued interest	<u>\$ 1,726,079</u>	<u>\$ -</u>

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

ENDRA Life Sciences Inc.
Notes to Consolidated Financial Statements
For the years ended December 31, 2017 and 2016

Note 1 – Nature of the Business

ENDRA Life Sciences Inc. (“ENDRA” or the “Company”) is developing a medical imaging technology based on the thermoacoustic effect that improves the sensitivity and specificity of clinical ultrasound.

On May 8, 2017, the Company effected a 1-for-3.5 reverse stock split (the “Reverse Split”) of the Company’s common stock, with no reduction in authorized capital stock. In the Reverse Split, every 3.5 outstanding shares of common stock became one (1) share of common stock. See Note 6 below.

All common stock and stock incentive plan information in these financial statements reflect the Reverse Split.

ENDRA was incorporated on July 18, 2007 as a Delaware corporation.

ENDRA Life Sciences Canada Inc. was organized under the laws of Ontario, Canada on July 6, 2017, and is wholly owned by the Company.

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Management makes estimates that affect certain accounts including deferred income tax assets, accrued expenses, fair value of equity instruments and reserves for any other commitments or contingencies. Any adjustments applied to estimates are recognized in the period in which such adjustments are determined.

Principles of Consolidation

The Company’s consolidated financial statements include all accounts of the Company and its consolidated subsidiary and/or entities as of reporting period ending date(s) and for the reporting period(s) then ended. All inter-company balances and transactions have been eliminated.

Basis of Presentation

The accompanying consolidated financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”).

Cash and Cash Equivalents

The Company considers all cash on hand and in banks, including accounts in book overdraft positions, certificates of deposit and other highly-liquid investments with maturities of one year or less, when purchased, to be cash and cash equivalents. As of December 31, 2017 and December 31, 2016, the Company had no cash equivalents. The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits.

Inventory

The Company’s inventory is stated at the lower of cost or estimated realizable value, with cost primarily determined on a weighted-average cost basis on the first-in, first-out (“FIFO”) method. The Company periodically determines whether a reserve should be taken for devaluation or obsolescence of inventory. As of December 31, 2017 and December 31, 2016, no such reserve was taken.

Capitalization of Fixed Assets

The Company capitalizes expenditures related to property and equipment, subject to a minimum rule, that have a useful life greater than one year for: (1) assets purchased; (2) existing assets that are replaced, improved or the useful lives have been extended; or (3) all land, regardless of cost. Acquisitions of new assets, additions, replacements and improvements (other than land) costing less than the minimum rule in addition to maintenance and repair costs, including any planned major maintenance activities, are expensed as incurred.

Capitalization of Intangible Assets

The Company records the purchase of intangible assets not purchased in a business combination in accordance with the ASC Topic 350.

Revenue Recognition

The Company recognizes revenue in accordance with the requirements of ASC 605-10-599, which directs that it should recognize revenue when (1) persuasive evidence of an arrangement exists (contracts); (2) delivery has occurred; (3) the seller's price is fixed or determinable (per the customer's contract); and (4) collectability is reasonably assured (based upon our credit policy). For products sold to end-users revenue is recognized when title has passed to the customer and collectability is reasonably assured; and no further efforts are required. Future revenue from anticipated new products will follow this same policy.

Income Taxes

The Company utilizes ASC 740, "Income Taxes," which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the tax basis of assets and liabilities and their financial reporting amounts based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is recorded when it is "more likely-than-not" that a deferred tax asset will not be realized.

The Company generated a deferred tax asset through net operating loss carry-forwards. However, a valuation allowance of 100% has been established due to the uncertainty of the Company's realization of the net operating loss carry forward prior to its expiration.

Research and Development Costs

The Company follows ASC 730-10, "Research and Development". Research and development costs are charged to the statement of operations as incurred. During the years ended December 31, 2017 and December 31, 2016, the Company incurred \$1,931,075 and \$495,677 of expenses related to research and development costs, respectively.

Net Earnings (Loss) Per Common Share

The Company computes earnings per share under ASC Subtopic 260-10, Earnings Per Share ("ASC 260-10"). Basic earnings (loss) per share is computed by dividing the net income (loss) attributable to the common stockholders (the numerator) by the weighted average number of shares of common stock outstanding (the denominator) during the reporting periods. Diluted loss per share is computed by increasing the denominator by the weighted average number of additional shares that could have been outstanding from securities convertible into common stock (using the "treasury stock" method), unless their effect on net loss per share is anti-dilutive. There were 3,208,262 and 1,346,441 potentially dilutive shares, which include outstanding common stock options, warrants, and convertible notes, as of December 31, 2017 and December 31, 2016, respectively.

The potential shares, which are excluded from the determination of basic and diluted net loss per share as their effect is anti-dilutive, are as follows:

	December 31, 2017	December 31, 2016
Options to purchase common stock	940,121	151,881
Warrants to purchase common stock	2,268,141	152,812
Convertible notes	-	1,041,748
Potential equivalent shares excluded	3,208,262	1,346,441

Fair Value Measurements

Disclosures about fair value of financial instruments require disclosure of the fair value information, whether or not recognized in our balance sheet, where it is practicable to estimate that value. As of December 31, 2017 and December 31, 2016, the amounts reported for cash, accrued liabilities and accrued interest approximated fair value because of their short maturities.

In accordance with ASC Topic 820, "Fair Value Measurements and Disclosures," the Company measures certain financial instruments at fair value on a recurring basis. ASC Topic 820 defines fair value, established a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Topic 820 established a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts of the Company's financial assets and liabilities, including cash, prepaid expenses, accounts payable, accrued expenses, and other current liabilities, approximate their fair values because of the short maturity of these instruments. The fair value of notes payable and convertible notes approximates their fair values since the current interest rates and terms on these obligations are the same as prevailing market rates.

Share-based Compensation

The Company's 2016 Omnibus Incentive Plan permits the grant of stock options and other share-based award to its employees, consultants and non-employee members of the board of directors covering up to 1,345,074 shares of common stock, of which approximately 500,000 remain available to be granted. The Company records share-based compensation in accordance with the provisions of the Share-based Compensation Topic of the FASB Codification. The guidance requires the use of option-pricing models that require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting charge is expensed using the straight-line attribution method over the vesting period. The Company has elected to use the calculated value method to account for the options it issued in 2017 (prior to commencement on June 28, 2017 of public trading in the Company's common stock) and in 2016. Under the Share-based Compensation Topic of the FASB Codification, a nonpublic entity that is unable to estimate the expected volatility of the price of its underlying share may measure awards based on a "calculated value," which substitutes the volatility of appropriate public companies (representative of the company's size and industry) as a bench mark for the volatility of the entity's own share price. Prior to June 28, 2017, there was no active market for the Company's common shares. The Company has used the historical closing values of these companies to estimate volatility, which was calculated to be 90%.

Stock compensation expense recognized during the period is based on the value of share-based awards that were expected to vest during the period adjusted for estimated forfeitures. The estimated fair value of grants of stock options and warrants to non-employees of the Company is charged to expense, if applicable, in the financial statements. These options vest in the same manner as the employee options granted under the stock incentive plan as described above.

Beneficial Conversion Feature

If the conversion feature of conventional convertible debt provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature ("BCF"). A BCF is recorded by the Company as a debt discount pursuant to ASC Topic 470-20 "Debt with Conversion and Other Options." In those circumstances, the convertible debt is recorded net of the discount related to the BCF and the Company amortizes the discount to interest expense over the life of the debt using the effective interest method.

Debt Discount

The Company determines if the convertible debenture should be accounted for as liability or equity under ASC 480, Liabilities — Distinguishing Liabilities from Equity. ASC 480 applies to certain contracts involving a company's own equity, and requires that issuers classify the following freestanding financial instruments as liabilities: mandatorily redeemable financial instruments, obligations that require or may require repurchase of the issuer's equity shares by transferring assets (e.g., written put options and forward purchase contracts), and certain obligations where at inception the monetary value of the obligation is based solely or predominantly on:

- A fixed monetary amount known at inception (for example, a payable settleable with a variable number of the issuer's equity shares with an issuance date fair value equal to a fixed dollar amount);
- Variations in something other than the fair value of the issuer's equity shares (for example, a financial instrument indexed to the S&P 500 and settleable with a variable number of the issuer's equity shares); or
- Variations inversely related to changes in the fair value of the issuer's equity shares (for example, a written put that could be net share settled).

If the entity determined the instrument meets the guidance under ASC 480, the instrument is accounted for as a liability with a respective debt discount. The Company records debt discounts in connection with raising funds through the issuance of promissory notes (see Note 5). These costs are amortized to noncash interest expense over the life of the debt. If a conversion of the underlying debt occurs, a proportionate share of the unamortized amounts is immediately expensed.

Going Concern

The Company's financial statements are prepared using accounting principles generally accepted in the United States ("U.S. GAAP") applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has limited commercial experience and had a cumulative net loss from inception to December 31, 2017 of \$17,895,435. The Company had working capital of \$5,033,939 as of December 31, 2017. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and to allow it to continue as a going concern. The accompanying financial statements for the period ended December 31, 2017 have been prepared assuming the Company will continue as a going concern. The Company's cash resources will likely be insufficient to meet its anticipated needs during the next twelve months. The Company will require additional financing to fund its future planned operations, including research and development and commercialization of its products.

The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it establishes a revenue stream and becomes profitable. Management's plans to continue as a going concern include raising additional capital through sales of equity securities and borrowing. However, management cannot provide any assurances that the Company will be successful in accomplishing any of its plans. If the Company is not able to obtain the necessary additional financing on a timely basis, the Company will be forced to delay or scale down some or all of its development activities or perhaps even cease the operation of its business. The ability of the Company to continue as a going concern is dependent upon its ability to successfully secure other sources of financing and attain profitable operations. There is substantial doubt about the ability of the Company to continue as a going concern within one year after the date that the financial statements are issued. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 is a comprehensive revenue recognition standard that will supersede nearly all existing revenue recognition guidance under current U.S. GAAP and replace it with a principle based approach for determining revenue recognition. Under ASU 2014-09, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The FASB has recently issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted only in annual reporting periods beginning after December 15, 2016, including interim periods therein. The standard can be adopted either retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). The Company has reviewed ASU 2014-09 and has determined that its adoption will have no impact on its financial position, results of operations or cash flows. The Company plans to adopt the provisions of this statement in the first quarter of fiscal 2018.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718) Scope of Modification Accounting ("ASU 2017-09"). The amendments in ASU 2017-09 provide 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. The adoption of ASU 2017-09, which will become effective for annual periods beginning after December 15, 2017 and for interim periods within those annual periods, is not expected to have any impact on the Company's financial statement presentation or disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases. ASU 2016-02 requires a lessee to record a right of use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. ASU 2016-02 is effective for all interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest period presented in the financial statements. The Company is currently evaluating the expected impact that the standard could have on its financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

Note 3 – Inventory

As of December 31, 2017 and 2016, inventory consisted of raw materials to be used in the assembly of a Nexus 128 system. As of December 31, 2017 and 2016 the Company had no orders pending for the sale of a Nexus 128 system.

Note 4 – Fixed Assets

As of December 31, 2017 and December 31, 2016, fixed assets consisted of the following:

	December 31, 2017	December 31, 2016
Computer equipment and fixtures	\$ 579,179	\$ 571,318
Accumulated depreciation	(337,630)	(276,150)
Fixed assets, net	<u>\$ 241,549</u>	<u>\$ 295,168</u>

Depreciation expense for the years ended December 31, 2017 and 2016 was \$61,481 and \$64,936, respectively.

Note 5 – Current Liabilities

As of December 31, 2017 and December 31, 2016, current liabilities consisted of the following:

	December 31, 2017	December 31, 2016
Accounts payable	\$ 780,261	\$ 227,744
Accrued payroll	40,578	105,258
Accrued employee benefits	27,375	29,552
Accrued interest	-	71,998
Notes payable	-	50,000
Convertible notes, related party, net of discount	-	99,804
Convertible notes, net of discount	-	800,172
Total	<u>\$ 848,214</u>	<u>\$ 1,384,528</u>

On January 28, 2016, the Company entered into promissory notes with three investors for a total amount of \$50,000. The notes matured one year from the issue date, accrued no interest and were payable at maturity. Prior to the maturity date, the Company and the promissory note holders agreed to extend the maturity date of all three notes to July 31, 2017, on the same terms as previously agreed. The Company accounted for imputed interest of \$1,480 for the year ended December 31, 2017, which was calculated at a rate of 8% per annum, consistent with other notes issued by the Company. During the year ended December 31, 2017, the promissory notes were repaid in full to all holders.

During 2016, the Company entered into convertible promissory notes with approximately 60 investors for a total principal amount of \$1,386,448, \$132,000 of which were purchased by related parties (the "2016 Notes"). On March 15, 2017, the Company extended the 2016 Notes offering by \$250,000. The extension was made available only to existing noteholders and obtained subscriptions for \$225,000. Pursuant to the terms of the 2016 Notes, noteholders holding a majority of the outstanding principal amount of the 2016 Notes elected to convert the principal and accrued interest on all outstanding 2016 Notes into shares of the Company's common stock at a conversion price of \$1.40 per share immediately prior to the Company's initial public offering. 1,232,859 shares of the Company's common stock were issued upon such conversion (see Note 6). In connection with the issuance of the 2016 Notes, the Company recorded a debt discount at an initial aggregate value of \$1,611,448, of which \$711,472 and \$899,976 was amortized during the years ended December 31, 2017 and 2016, respectively, resulting in a debt discount balance of \$0 as of December 31, 2017. The Company had interest expenses of \$42,633 and \$71,988 for the years ended December 31, 2017 and 2016, respectively.

Note 6 – Capital Stock

At December 31, 2017, the authorized capital of the Company consisted of 60,000,000 shares of capital stock, consisting of 50,000,000 shares of common stock with a par value of \$0.0001 per share, and 10,000,000 shares of preferred stock with a par value of \$0.0001 per share. As of December 31, 2017, there were 3,923,027 shares of common stock issued and outstanding and no preferred stock outstanding.

Reverse Stock Split

On May 8, 2017, the Company filed a certificate of amendment (the "Certificate of Amendment") to its certificate of incorporation with the Secretary of State of the State of Delaware to effect the Reverse Split of the Company's common stock, with no reduction in authorized capital stock. Pursuant to the terms of the Certificate of Amendment, the Reverse Split became effective at 11:59 p.m. Eastern Time on May 8, 2017. In the Reverse Split, every 3.5 outstanding shares of common stock became one share of common stock. No fractional shares were issued in connection with the Reverse Split. Subject to the terms of the Certificate of Amendment, stockholders who were otherwise entitled to receive a fractional share of common stock received one whole share of common stock.

The Reverse Split was previously approved by holders of a majority of the Company's issued and outstanding common stock. All common stock and stock incentive plan information in these consolidated financial statements has been restated to reflect this split.

Initial Public Offering of Units

The Company's Registration Statement on Form S-1, as amended (Reg. No. 333-214724), was declared effective by the Securities and Exchange Commission (the "SEC") on May 8, 2017, and the Company's Registration Statement on Form S-1 (Reg. No. 333-217788), which was filed on May 8, 2017 with the SEC pursuant to Rule 462(b) of the Securities Act of 1933, as amended (the "Securities Act"), became effective upon filing. These registration statements registered the securities offered in the Company's initial public offering (the "IPO"). In the IPO, the Company sold 1,932,000 units at a price to the public of \$5.00 per unit, including the full exercise of the underwriters' option to purchase additional units. Each unit consisted of one share of the Company's common stock and a warrant to purchase a share of the Company's common stock at an exercise price of \$6.25 per share. The warrants terminate on May 12, 2022.

The IPO closed on May 12, 2017 and the underwriters exercised their overallotment option as of May 22, 2017, as a result of which the Company raised through the IPO net proceeds of approximately \$8.6 million after deducting approximately \$773,000 in underwriting discounts, commissions and expenses and approximately \$297,000 in offering expenses payable by the Company. National Securities Corporation and Dougherty & Company LLC were the underwriters of the IPO. No payments were made by the Company to its directors or officers or persons owning ten percent or more of its common stock or to their associates, or to the Company's affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

The shares of common stock and warrants initially traded together on the Nasdaq Capital Market as units under the symbol "NDRAU".

Effective at 12:01 a.m. on June 28, 2017, each of the Company's units issued in the IPO separated into one share of the Company's common stock and a warrant to purchase a share of the Company's common stock. Following separation, the common stock and warrants included in the units commenced trading on The Nasdaq Capital Market separately under the symbols "NDRA" and "NDRAW," respectively, and trading of the units under the symbol "NDRAU" was suspended.

Conversion of Convertible Notes

In connection with the funding of the IPO, on May 12, 2017, the principal and interest due under the Company's convertible notes, in an aggregate amount of \$1,726,079, was converted into 1,232,859 shares of the Company's common stock. The purchasers of the convertible notes are subject to lock-up requirements with respect to the conversion shares for periods that expire on May 9, 2018.

Common Stock Issued for Services

During the year ended December 31, 2017, the Company issued 18,833 shares of common stock for services valued at \$94,165 to a firm owned by David R. Wells, the Company's Chief Financial Officer.

During the year ended December 31, 2017, the Company issued 16,000 shares of common stock for services valued at \$57,440, \$9,573 of which was expensed as of December 31, 2017, based on the duration of the contract. The certificates for these shares were issued in January 2018.

Note 7 – Stock Options and Warrants

Stock options are awarded to the Company's employees, consultants and non-employee members of the board of directors under the 2016 Omnibus Incentive Plan and are generally granted with an exercise price equal to the market price of the Company's common stock at the date of grant. The fair value of these stock options granted by the Company during the year ended December 31, 2017 was determined to be \$3,250,110 using the Black-Scholes-Merton option-pricing model based on the following assumptions: (i) volatility rate of 90%, (ii) discount rate of 0%, (iii) zero expected dividend yield, and (iv) expected life of 4 to 8 years. A summary of option activity under the Company's stock options as of December 31, 2017, and changes during the year then ended is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Balance outstanding at December 31, 2016	151,890	\$ 9.99	2.47
Granted	803,216	4.91	7.27
Exercised	-	-	-
Forfeited	-	-	-
Cancelled or expired	(14,985)	10.02	-
Balance outstanding at December 31, 2017	940,121	\$ 5.65	6.46
Exercisable at December 31, 2017	206,308	\$ 7.98	3.74

During the year ended December 31, 2017, in connection with the closing of the IPO, the Company issued to the underwriters and their designees warrants to purchase an aggregate of 154,560 shares of the Company's common stock (the "Underwriters' Warrants") at an exercise price of \$6.25 per share with an expiration date of May 8, 2022. The Underwriters' Warrants become exercisable on November 8, 2017.

During the year ended December 31, 2017, the Company granted warrants to purchase 10,000 shares of common stock with an exercise price of \$5.50 per share for services. The warrants vest in six monthly installments beginning on June 12, 2017. The fair value of these warrants was determined to be \$27,779 using the Black-Scholes-Merton option-pricing model based on the following assumptions: (i) volatility rate of 90%, (ii) discount rate of 0%, (iii) zero expected dividend yield, and (iv) expected life of 3 years. During the year ended December 31, 2017, \$27,779 was expensed.

During the year ended December 31, 2017, the Company granted warrants to purchase 20,000 shares of common stock with an exercise price of \$4.49 per share for services. The warrants vest in six monthly installments beginning on December 28, 2017. The fair value of these warrants was determined to be \$29,565 using the Black-Scholes-Merton option-pricing model based on the following assumptions: (i) volatility rate of 70%, (ii) discount rate of 0%, (iii) zero expected dividend yield, and (iv) expected life of 3 years. During the year ended December 31, 2017, \$4,928 was expensed.

The following table summarizes all stock warrant activity of the Company for the year ended December 31, 2017:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Balance outstanding at December 31, 2016	152,828	\$ 5.41	3.30
Granted	2,116,563	6.23	4.34
Exercised	-	-	-
Forfeited	-	-	-
Expired	(1,250)	10.02	-
Balance outstanding at December 31, 2017	2,268,141	\$ 7.09	4.21
Exercisable at December 31, 2017	2,251,475	\$ 7.10	4.22

Note 8 – Income Taxes

The U.S. tax reform bill that Congress voted to approve Dec. 20, 2017, also known as the "Tax Cuts and Jobs Act", made sweeping modifications to the Internal Revenue Code, including a much lower corporate tax rate, changes to credits and deductions, and a move to a territorial system for corporations that have overseas earnings.

The act replaced the prior-law graduated corporate tax rate, which taxed income over \$10 million at 35%, with a flat rate of 21%.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2017 and 2016 are summarized below.

	2017	2016
Net operating loss carryforward	\$ (4,288,410)	\$ (3,881,317)
Stock based compensation	-	1,980
Fair value of options	268,792	78,311
Total deferred tax assets	(4,019,618)	3,801,026
Valuation allowance	4,019,618	3,801,026
Net deferred tax asset	-	-

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2017 and 2016, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized, and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

For U.S. purposes, the Company has not completed its evaluation of NOL utilization limitations under Internal Revenue Code, as amended (the "Code") Section 382, change of ownership rules. If the Company has had a change in ownership, the NOL's would be limited as to the amount that could be utilized each year, based on the Code, as amended.

No federal tax provision has been provided for the years ended December 31, 2017 and 2016 due to the losses incurred during such periods. Reconciled below is the difference between the income tax rate computed by applying the U.S. federal statutory rate and the effective tax rate for the years ended December 31, 2017 and 2016.

	2017	2016
U.S. federal statutory income tax	-34.00%	-34.00%
State tax, net of federal tax benefit	-5.80%	-5.80%
Stock based compensation	0.00%	0.00%
Change in valuation allowance	39.80%	39.80%
Effective tax rate	0.00%	0.00%

At December 31, 2017, the Company has available net operating loss carryforwards for federal and state income tax purposes of approximately \$13.8 million and \$10.2 million, respectively, which, if not utilized earlier, expire through 2037.

Note 9 – Commitments & Contingencies

Office Lease

Effective January 1, 2015, the Company entered into an office lease agreement with Green Court, LLC, a Michigan limited liability company, for approximately 3,657 rentable square feet of space, for the initial monthly rent of \$5,986, which commenced on January 1, 2015 for an initial term of 60 months and was revised on October 10, 2017 to increase the space to 3,950 square feet and the monthly rent to \$7,798. Under the terms of the lease the Company has an option on the same space for an additional 60-month term. Future minimum payments under this lease are as follows:

2018	77,348
2019	79,269
Total	<u>\$ 156,617</u>

For the years ended December 31, 2017 and 2016, the Company incurred rent expenses of \$52,527 and \$55,687, respectively.

Employment and Consulting Agreements

Francois Michelin. Effective May 12, 2017, the Company entered into an amended and restated employment agreement with Francois Michelin, our Chief Executive Officer and Chairman of the board of directors. The term of the employment agreement runs through December 31, 2019. The employment agreement provides for an annual base salary of \$325,000. Under the employment agreement, Mr. Michelin is eligible for an annual cash bonus based upon achievement of performance-based objectives established by the board of directors. Pursuant to Mr. Michelin's employment agreement, upon the closing of our initial public offering he was granted options to purchase 307,310 shares of common stock. The options have an exercise price of \$5.00 per share of common stock and vest in three equal annual installments beginning on May 12, 2018. Upon termination without cause, any portion of Mr. Michelin's options scheduled to vest within 12 months will automatically vest, and upon termination without cause within 12 months following a change of control, the entire unvested portion of the option will automatically vest. Upon termination for any other reason, the entire unvested portion of the option will terminate.

If Mr. Michelin's employment is terminated by the Company without cause, Mr. Michelin will be entitled to receive 12 months' continuation of his current base salary and a lump sum payment equal to 12 months of continued healthcare coverage (or 24 months' continuation of his current base salary and a lump sum payment equal to 24 months of continued healthcare coverage if such termination occurs within one year following a change in control).

Under his employment agreement, Mr. Michelin is eligible to receive benefits that are substantially similar to those of the Company's other senior executive officers.

Michael Thornton. Effective May 12, 2017, the Company entered into an amended and restated employment agreement with Michael Thornton, our Chief Technology Officer. The term of the employment agreement runs through December 31, 2019. The employment agreement provides for an annual base salary of \$245,000. Under the employment agreement, Mr. Thornton is eligible for an annual cash bonus based upon achievement of performance-based objectives established by the board of directors. Pursuant to Mr. Thornton's employment agreement, upon the closing of our initial public offering he was granted options to purchase 313,338 shares of common stock. The options have an exercise price of \$5.00 per share of common stock and vest in three equal annual installments beginning on May 12, 2018. Upon termination without cause, any portion of Mr. Thornton's option scheduled to vest within 12 months will automatically vest, and upon termination without cause within 12 months following a change of control, the entire unvested portion of the option will automatically vest. Upon termination for any other reason, the entire unvested portion of the option will terminate.

If Mr. Thornton's employment is terminated by the Company without cause, Mr. Thornton will be entitled to receive 12 months' continuation of his current base salary and a lump sum payment equal to 12 months of continued healthcare coverage (or 24 months' continuation of his current base salary and a lump sum payment equal to 24 months of continued healthcare coverage if such termination occurs within one year following a change in control).

Under his employment agreement, Mr. Thornton is eligible to receive benefits that are substantially similar to those of the Company's other senior executive officers.

David R. Wells. On May 12, 2017, the Company entered into a consulting agreement with StoryCorp Consulting ("StoryCorp"), pursuant to which David Wells provides services to the Company as its Chief Financial Officer. Pursuant to the consulting agreement, the Company pays to StoryCorp a monthly fee of \$9,000. Additionally, pursuant to the consulting agreement, the Company granted to Mr. Wells a stock option to purchase 15,000 shares of common stock in connection with the closing of our initial public offering, having an exercise price per share equal to \$5.00 and vesting in twelve equal quarterly installments, and, for so long as the consulting agreement is in place, will grant to Mr. Wells a stock option to purchase the same number of shares of common stock with the same terms on each annual anniversary of the date of the consulting agreement.

Litigation

From time to time the Company may become a party to litigation in the normal course of business. Management believes that there are no current legal matters that would have a material effect on the Company's financial position or results of operations.

Note 10 – Subsequent Events

Subsequent to December 31, 2017, the Company granted warrants to purchase 20,000 shares of common stock with an exercise price of \$5.50 per share for services.

Subsequent to December 31, 2017, the Company awarded stock options to purchase 38,790 shares of common stock with an exercise price of \$4.95 per share to its consultants and non-employee members of the board of directors.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, management performed, with the participation of our principal executive and principal financial officers, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on the evaluation, our principal executive and principal financial officers concluded that, as of December 31, 2017, our disclosure controls and procedures were not effective due to a material weakness in internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We identified the following material weakness as of December 31, 2017: insufficient personnel resources within the accounting function to segregate the duties over financial transaction processing and reporting.

To remediate our internal control weakness, management intends to implement the following measures:

- Add sufficient accounting personnel or outside consultants to properly segregate duties and to effect a timely, accurate preparation of the financial statements.
- Upon the hiring of additional accounting personnel or outside consultants, develop and maintain adequate written accounting policies and procedures.

The additional hiring is contingent upon our efforts to obtain additional funding and the results of our operations. Management expects to secure funds in the coming fiscal year but provides no assurances that it will be able to do so.

Management's Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth the names and ages of all of our executive officers and directors. Our officers are appointed by, and serve at the pleasure of, the board of directors.

Name	Age	Position
Francois Michelin	52	Chief Executive Officer and Chairman
Michael Thornton	49	Chief Technology Officer
David Wells	55	Chief Financial Officer
Anthony DiGiandomenico	51	Director
Dr. Sanjiv Sam Gambhir	55	Director
Michael Harsh	63	Director
Alexander Tokman	56	Director

Biographical information with respect to our executive officers and directors is provided below. There are no family relationships between any of our executive officers or directors.

Francois Michelin – Chief Executive Officer and Chairman

Francois Michelin joined ENDRA as Chief Executive Officer and Chairman of our board of directors in 2015. He has 20 years of healthcare technology experience in general management, operations, strategy and marketing across the diagnostic imaging, surgical instrument and dental sectors.

From 2012 to 2014, Mr. Michelin served as Vice President of Global Marketing for the 3i division of Biomet, Inc. (now Zimmer Biomet Holdings, Inc.), a provider of oral reconstruction technologies, where he was responsible for the upstream and downstream development of the division's global portfolio. From 2004 to 2011, Mr. Michelin served as Group Director of Global Services and Visualization for Smith & Nephew plc's Advanced Surgical Devices division, where he led in the B2B service and capital equipment sectors, and had responsibility over the financial performance of these as well. From 1997 to 2004, Mr. Michelin worked at GE Healthcare in a variety of global upstream and downstream marketing roles.

Mr. Michelin received an MBA from Carnegie-Mellon University and a BA in Economics from the University of Chicago. He has also earned his Six Sigma Black Belt certification. Mr. Michelin's extensive industry and executive experience and his intimate understanding of our business as our Chief Executive Officer, position him well to serve as a member of our board of directors.

Michael Thornton – Chief Technology Officer

Prior to joining ENDRA as Chief Technology Officer in 2007, Michael Thornton was a founder and President of Enhanced Vision Systems Corp., or EVS, a developer and supplier of medical imaging equipment to the pharmaceutical, biotech, and academic sectors.

In 2002, EVS was acquired by General Electric Company and was integrated into the Functional and Molecular Imaging business unit of GE Medical Systems (now GE Healthcare, a subsidiary of General Electric Company). Following the acquisition of EVS by GE Medical Systems, Mr. Thornton held a number of positions at GE Healthcare, including Sales Manager, Global Product Manager, and Site Leader. He was a member of the leadership team that expanded the pre-clinical imaging business to include: computed tomography, optical, and positron emission tomography imaging technologies, with global market reach. He is also a founder of Volumetrics Medical Corp., a developer and manufacturer of quality assurance devices for diagnostic imaging.

Prior to founding EVS, Mr. Thornton developed medical imaging related technologies at the Robarts Research Institute (London, Ontario, Canada) for which he obtained an MSc in Electrical Engineering from the University of Western Ontario. Mr. Thornton also holds a BSc in Electrical Engineering from the University of Toronto and is a member of the American Association of Physicists in Medicine.

David Wells – Chief Financial Officer

David Wells became our Chief Financial Officer on an interim basis in 2014 and on a continuing basis in 2017. He possesses over 30 years of experience in finance, operations and administrative positions. While mainly focused on technology companies, Mr. Wells has also worked in the water treatment, supply-chain management, manufacturing and professional services industries.

Mr. Wells is the founder of Wells Compliance Group, a technology-based services firm supporting the financial reporting needs of publicly traded companies and privately held firms whose investor or shareholder base requires timely GAAP-compliant financial reporting. Through StoryCorp Consulting (d/b/a/ Wells Compliance Group), Mr. Wells consults with several emerging growth companies and has served as the principal financial officer of Mount Tam Biotechnologies, Inc., a biopharmaceutical company (August 2015 to April 2016), Content Checked Holdings, Inc., a technology company (April 2015 to November 2016), and Loton, Corp., a media company (February 2016 to present). From 2009 to 2013, he was the President, CFO and a Director of Sionix Corporation, a publicly traded water treatment company.

Mr. Wells holds an MBA from Pepperdine University and a BS in Finance and Entrepreneurship from Seattle Pacific University.

Anthony DiGiandomenico – Director

Anthony DiGiandomenico joined our board of directors in 2013. A co-founder of MDB Capital Group LLC, Mr. DiGiandomenico focuses on corporate finance and capital formation for growth-oriented companies. He has participated in all areas of corporate finance including private capital, public offerings, PIPEs, business consulting and strategic planning, and mergers and acquisitions.

Mr. DiGiandomenico has also worked on a wide range of transactions for growth-oriented companies in biotechnology, nutritional supplements, manufacturing and entertainment industries. Prior to forming MDB Capital Group LLC in 1997, Mr. DiGiandomenico served as President and CEO of the Digian Company, a real estate development company. Currently, Mr. DiGiandomenico serves on the board of directors of Cue Biopharma, Inc.

Mr. DiGiandomenico holds an MBA from the Haas School of Business at the University of California, Berkeley and a BS in Finance from the University of Colorado. Mr. DiGiandomenico's financial expertise, general business acumen and significant executive leadership experience position him well to make valuable contributions to our board of directors.

Dr. Sanjiv Sam Gambhir – Director

Dr. Sanjiv Sam Gambhir joined our board of directors in 2008. He is the Virginia & D.K. Ludwig Professor of Cancer Research and the Chair of Radiology at Stanford University School of Medicine. He also heads the Canary Center at Stanford for Cancer Early Detection and directs the Molecular Imaging Program at Stanford (MIPS).

He received an MD/PhD from the UCLA Medical Scientist Training Program. He has many publications in the field and numerous patents pending or granted. He has developed and clinically translated several multimodality molecular imaging strategies including imaging of gene and cell therapies. He has also pioneered imaging areas such as Bioluminescence Resonance Energy Transfer (BRET), split-reporter technology, Raman imaging in vivo, Molecular Photoacoustic imaging, PET reporter genes, and novel in vitro and in vivo strategies for the early detection of cancer.

Dr. Gambhir serves on numerous academic advisory boards for universities around the world and also served as a member of the Board of Scientific Advisors of the National Cancer Institute from 2004 to 2012. He has also founded or co-founded several startups in the diagnostics space. Among his many awards are the George Von Hevesy Prize and the Paul C. Aebersold Award for outstanding achievement in basic nuclear medicine science from the Society of Nuclear Medicine, Outstanding Researcher Award from the Radiological Society of Northern America, the Distinguished Clinical Scientist Award from the Doris Duke Charitable Foundation, the Holst Medal, the Tesla Medal, and the Hounsfield Medal from Imperial College, London. He was elected to the Institute of Medicine of the U.S. National Academies in 2008. Dr. Gambhir's unique and extensive scientific and technical expertise positions him well to serve on our board of directors.

Michael Harsh – Director

Michael Harsh joined our board of directors in 2015. He has 39 years' experience in healthcare technology, focused on diagnostic imaging. Mr. Harsh was most recently GE Healthcare's Vice President and Chief Technology Officer, leading its global science and technology organization and research and development teams in diagnostics, healthcare IT and life sciences.

In 2004, Mr. Harsh was named Global Technology Leader – Imaging Technologies Lab at the GE Global Research Center, where he led the research for imaging technologies across the company as well as the research associated with computer visualization/image analysis and superconducting systems. He led the Engineering division for GE Industrial and Enterprise Solutions from 2006 to 2009. Mr. Harsh was named an officer of General Electric Company in November 2006. Mr. Harsh is the co-founder of Terapede Systems, a digital x-ray detector startup, a member of the boards of directors of FloDesign Sonics, Imation Biosystems, and EmOpti as well as a member the Radiological Society of North America ("RSNA"), Research & Education Foundation Board of Trustees. He is also a McKinsey Senior Advisor and a consultant in the medical device industry.

Mr. Harsh is a graduate of Marquette University, where he earned a bachelor's degree in Electrical Engineering. He holds numerous U.S. patents in the field of medical imaging and instrumentation. In 2008, Mr. Harsh was elected to the American Institute for Medical and Biological Engineering College of Fellows for his significant contributions to the medical and biological engineering field. Mr. Harsh's extensive industry, executive and board experience position him well to serve on our board of directors.

Alexander Tokman – Director

Alexander Tokman joined our board of directors in 2008. He has served as President, Chief Executive Officer, and a director of Microvision, Inc., a publicly traded laser beam scanning projection and imaging company, since January 2006.

Previously, Mr. Tokman completed a 10+ year tenure as an executive with GE Healthcare, where he led several global businesses, most recently as a General Manager of its Global Molecular Imaging and Radiopharmacy multi-technology business unit from 2003 to 2005.

Between 1995 and 2003, Mr. Tokman served in various leadership roles at GE Healthcare, where he led the definition and successful commercialization of several product segments, including PET/CT, which generated over \$500 million of revenue within the first three years of its launch.

Mr. Tokman is a certified Six Sigma and Design for Six Sigma (DFSS) Black Belt and Master Black Belt and as one of General Electric Company's Six Sigma pioneers, he drove the quality culture change across GE Healthcare in the late 1990s. From 1989 to 1995, Mr. Tokman served as development programs lead and a head of Industry and Regional Development at Tracor Applied Sciences. Mr. Tokman has both an MS and BS in Electrical Engineering from the University of Massachusetts, Dartmouth. Mr. Tokman's industry expertise and significant executive leadership and director experience position him well to make valuable contributions to our board of directors.

Director Independence

Our board of directors has determined that Anthony DiGiandomenico, Dr. Sanjiv Sam Gambhir, Michael Harsh and Alexander Tokman are "independent directors" as such term is defined by Nasdaq Marketplace Rule 5605(a)(2). We have established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of Mr. DiGiandomenico, Mr. Harsh and Mr. Tokman serve as members of the Audit Committee and Compensation Committee. Mr. Gambhir, Mr. Harsh and Mr. Tokman serve as members of the Nominating and Corporate Governance Committee. Our board of directors has determined that Mr. DiGiandomenico is an audit committee financial expert, as defined under the applicable rules of the SEC, and that all members of the Audit Committee are "independent" within the meaning of the applicable Nasdaq listing standards and the independence standards of Rule 10A-3 of the Exchange Act. Each of the members of the Audit Committee meets the requirements for financial literacy under the applicable rules and regulations of the SEC and The Nasdaq Stock Market.

Scientific Advisory Board

Our Scientific Advisory Board members work with our management team in the planning, development and execution of scientific and business strategies. It reviews, and advises management on our progress in research and clinical development as well as new scientific perspectives.

Jonathan Rubin, MD, PhD – Scientific Advisor

Dr. Jonathan Rubin is the Martel Collegiate Professor of Radiology and Section Head for Ultrasound and Abdominal Interventional Radiology at the University of Michigan Medical School.

Dr. Rubin has over 200 peer-reviewed publications, over 125 invited presentations, and 10 patents. In 2005 he was awarded the University of Michigan Medical School Innovation Award. In 2007 he won the American Institute of Ultrasound in Medicine Joseph H. Holmes Clinical Pioneer Award. In 2011 he received the Society of Radiologists in Ultrasound Lawrence Mack Lifetime Achievement Award.

Dr. Rubin received a BA in Chemistry from the University of Utah. He received an MD from the University of Chicago Pritzker School of Medicine and a PhD in Biophysics and Theoretical Biology from the University of Chicago. From 1979 to 1984, Dr. Rubin was the director of the Section of Body Computed Tomography and Ultrasound Imaging in the Department of Radiology at the University of Chicago.

Dr. Jing Gao, MD – Scientific Advisor

Dr. Jing Gao is currently the Director of Ultrasound in Education and Research at Rocky Vista University-Southern Utah and the Adjunct Research Assistant Professor of Radiology at Weill Cornell Medicine in New York, NY. Dr. Gao brings over 30 years of clinical and research experience in abdominal ultrasound, in both the United States and China.

Dr. Gao completed her medical education at Changchun and Dalian Medical Colleges in China. Besides her post at Cornell, Dr. Gao is Deputy President and guest professor at the Dalian University International Institute of Medical Imaging in China. She is also a guest professor at Capital Medical University and Chongqing Medical University in China.

Her numerous honors and professional affiliations include being named one of China's Top 100 Ultrasound Physicians by the Chinese Association of Medical Imaging Technology. She is a Fellow of the Chinese Association of Ultrasound in Medicine and Biology, a Fellow of the American Institute of Ultrasound in Medicine and an Editorial Board Member of Clinical Imaging and Ultrasound in Medicine and Biology (Elsevier).

Dr. Gao has numerous peer reviewed publications in the areas of liver, spleen, kidney, and skeletal muscle diseases and quantitative ultrasound imaging.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who own more than ten percent of a registered class of our equity securities to file reports of ownership and changes in ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all such filings. Based solely on our review of copies of such filings, we believe that all reporting persons complied on a timely basis with all Section 16(a) filing requirements during the year ended December 31, 2017, except that: (i) each of directors and executive officers failed to timely file a Form 3 upon the effectiveness of the registration of our common stock under Section 12(b) of the Exchange Act, (ii) Alexander Tokman filed one late Form 4 with respect to the granting of stock options, (iii) Anthony DiGiandomenico filed one late Form 4 with respect to the conversion of a convertible promissory note into common stock and the granting of stock options, and (iv) Sanjiv Gambhir filed one late Form 4 with respect to the granting of stock options.

Code of Business Conduct and Ethics

We have in place a Code of Business Conduct and Ethics (the "Code of Ethics") that applies to all of our directors, officers and employees. The Code of Ethics is designed to deter wrongdoing and to promote:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in other public communications that we make;
- compliance with applicable governmental laws, rules and regulations;
- the prompt internal reporting of violations of the Code of Ethics to an appropriate person identified in the Code of Ethics; and
- accountability for adherence to the Code of Ethics.

A current copy of the Code of Ethics is available at www.endrainc.com. A copy may also be obtained, free of charge, from us upon a request directed to ENDRA Life Sciences, Inc., 3600 Green Court, Suite 350, Ann Arbor, Michigan 48105, attention: Investor Relations. We intend to disclose any amendments to or waivers of a provision of the Code of Ethics required to be disclosed by applicable SEC rules by posting such information on our website available at www.endrainc.com and/or in our public filings with the SEC.

Item 11. Executive Compensation

Our compensation philosophy is to offer our executive officers compensation and benefits that are competitive and meet our goals of attracting, retaining and motivating highly skilled management, which is necessary to achieve our financial and strategic objectives and create long-term value for our stockholders. We believe the levels of compensation we provide should be competitive, reasonable and appropriate for our business needs and circumstances. Our board of directors uses benchmark compensation studies in determining compensation elements and levels. The principal elements of our executive compensation program have to date included base salary, annual bonus opportunity and long-term equity compensation in the form of stock options. We believe successful long-term Company performance is more critical to enhancing stockholder value than short-term results. For this reason and to conserve cash and better align the interests of management and our stockholders, we emphasize long-term performance-based equity compensation over base annual salaries.

The following table sets forth information concerning the compensation earned by the individual that served as our principal executive officer during 2017 and our two most highly compensated executive officers other than the individual who served as our principal executive officer during 2017 (collectively, the "named executive officers"):

2017 Summary Compensation Table

Name & Position	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Francois Michelin	2017	347,452(2)	-	-	-	347,452
Chief Executive Officer	2016	262,152	-	-	-	262,152
Michael Thornton	2017	272,086(3)	-	-	-	272,086
Chief Technology Officer	2016	218,056	-	-	-	218,056
David R. Wells (4)	2017	92,000	-	94,165	-	186,165
Chief Financial Officer	2016	60,000	-	-	-	60,000

- (1) The amounts shown in this column indicate the grant date fair value of option awards granted in the subject year computed in accordance with FASB ASC Topic 718. For additional information regarding the assumptions made in calculating these amounts, see notes 2 and 7 to our audited financial statements included herein.
- (2) Includes a payment for salary accrued during 2016 of \$53,819 .
- (3) Includes a payment for salary accrued during 2016 of \$51,438.
- (4) Represents fees earned by StoryCorp Consulting (d/b/a Wells Compliance Group). Pursuant to the consulting agreement described below, we issued 18,833 shares of our common stock valued at \$94,165 in 2017.

Outstanding Equity Awards at 2017 Fiscal Year End

The following table provides information regarding equity awards held by the named executive officers as of December 31, 2017.

Name	Option Awards					
	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price (\$)	Option Expiration Date
Francois Michelin	23,665	(1)	11,833		10.01	7/1/20
Chief Executive Officer	-	(2)	307,310		5.00	5/12/25
	-	(2)	31,960		4.55	5/12/25
Michael Thornton	29,471		-		10.01	11/1/18
Chief Technology Officer	-	(2)	313,338		5.00	5/12/25
	-	(2)	31,960		4.55	5/12/25
David Wells	2,500	(3)	12,500		5.00	5/12/21
Chief Financial Officer	7,000		-		5.00	5/12/22

(1) These options vest in three equal annual installments beginning on July 1, 2016.

(2) These options vest in three equal annual installments beginning on May 12, 2018.

(3) These options vest in twelve equal quarterly installments beginning on August 12, 2017.

Employment Agreements and Change of Control Agreements

Employment Agreements

The following is a summary of the employment arrangements with our executive officers as currently in effect.

Francois Michelin. Effective May 12, 2017, the Company entered into an amended and restated employment agreement with Francois Michelin, our Chief Executive Officer and Chairman of our board of directors. The term of the employment agreement runs through December 31, 2019. The employment agreement provides for an annual base salary of \$325,000. Under the employment agreement, Mr. Michelin is eligible for an annual cash bonus based upon achievement of performance-based objectives established by our board of directors. Pursuant to Mr. Michelin's employment agreement, upon the closing of our initial public offering he was granted options to purchase 307,310 shares of common stock. The options have an exercise price of \$5.00 per share of common stock and vest in three equal annual installments beginning on May 12, 2018. Upon termination without cause, any portion of Mr. Michelin's options scheduled to vest within 12 months will automatically vest, and upon termination without cause within 12 months following a change of control, the entire unvested portion of the option will automatically vest. Upon termination for any other reason, the entire unvested portion of the option will terminate.

If Mr. Michelin's employment is terminated by the Company without cause, Mr. Michelin will be entitled to receive 12 months' continuation of his current base salary and a lump sum payment equal to 12 months of continued healthcare coverage (or 24 months' continuation of his current base salary and a lump sum payment equal to 24 months of continued healthcare coverage if such termination occurs within one year following a change in control).

Under his employment agreement, Mr. Michelin is eligible to receive benefits that are substantially similar to those of the Company's other senior executive officers.

Michael Thornton. Effective May 12, 2017, the Company entered into an amended and restated employment agreement with Michael Thornton, our Chief Technology Officer. The term of the employment agreement runs through December 31, 2019. The employment agreement provides for an annual base salary of \$245,000. Under the employment agreement, Mr. Thornton is eligible for an annual cash bonus based upon achievement of performance-based objectives established by our board of directors. Pursuant to Mr. Thornton's employment agreement, upon the closing of our initial public offering he was granted options to purchase 313,338 shares of common stock. The options have an exercise price of \$5.00 per share of common stock and vest in three equal annual installments beginning on May 12, 2018. Upon termination without cause, any portion of Mr. Thornton's option scheduled to vest within 12 months will automatically vest, and upon termination without cause within 12 months following a change of control, the entire unvested portion of the option will automatically vest. Upon termination for any other reason, the entire unvested portion of the option will terminate.

If Mr. Thornton's employment is terminated by the Company without cause, Mr. Thornton will be entitled to receive 12 months' continuation of his current base salary and a lump sum payment equal to 12 months of continued healthcare coverage (or 24 months' continuation of his current base salary and a lump sum payment equal to 24 months of continued healthcare coverage if such termination occurs within one year following a change in control).

Under his employment agreement, Mr. Thornton is eligible to receive benefits that are substantially similar to those of the Company's other senior executive officers.

David R. Wells. On May 12, 2017, the Company entered into a consulting agreement with StoryCorp Consulting ("StoryCorp"), pursuant to which David Wells provides services to the Company as its Chief Financial Officer. Pursuant to the consulting agreement, the Company pays to StoryCorp a monthly fee of \$9,000. Additionally, pursuant to the consulting agreement, the Company granted to Mr. Wells a stock option to purchase 15,000 shares of common stock in connection with the closing of our initial public offering, having an exercise price per share equal to \$5.00 and vesting in twelve equal quarterly installments, and, for so long as the consulting agreement is in place, will grant to Mr. Wells a stock option to purchase the same number of shares of common stock with the same terms on each annual anniversary of the date of the consulting agreement.

Director Compensation

Effective on May 12, 2017 the Company adopted a non-employee director compensation policy pursuant to which our non-employee directors receive on an annual basis a \$36,000 retainer paid in cash and an annual equity award with a value of \$30,000. The equity award consists of a stock option grant made on the first trading day following December 31 of each year covering a number of shares of common stock equal to \$30,000 divided by the closing price of its common stock on such date which vests in full on the one year anniversary of grant; provided, the grants for 2017 were made on May 12, 2017 upon the closing of the Company's initial public offering and each covered 6,000 shares of common stock.

The following table sets forth information with respect to compensation earned by or awarded to each of our non-employee directors who served on our board of directors during the fiscal year ended December 31, 2017:

Name	Paid in Cash (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Anthony DiGiandomenico	14,129	48,696	-	62,825
Dr. Sanjiv Sam Gambhir	14,129	48,696	-	62,825
Michael Harsh	14,129	48,696	-	62,825
Alexander Tokman	14,129	48,696	-	62,825

- (1) The amounts shown in this column indicate the grant date fair value of option awards granted in the subject year computed in accordance with FASB ASC Topic 718. For additional information regarding the assumptions made in calculating these amounts, see note 7 to our audited financial statements included herein. The following table shows the number of shares subject to outstanding option awards held by each non-employee director as of December 31, 2017:

Name	Shares subject to Outstanding Stock Option Awards (#)
Anthony DiGiandomenico	23,157
Dr. Sanjiv Sam Gambhir	34,893
Michael Harsh	23,432
Alexander Tokman	27,231

2016 Omnibus Incentive Plan

In September 2016, our board of directors and stockholders approved the 2016 Omnibus Incentive Plan, which permits the grant of stock options and shares to our employees, consultants and non-employee members of our board of directors for up to 1,345,074 shares of common stock.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters.

We have set forth in the following table certain information regarding our common stock beneficially owned by (i) each stockholder we know to be the beneficial owner of 5% or more of our outstanding common stock, (ii) each of our directors and named executive officers, and (iii) all executive officers and directors as a group. Generally, a person is deemed to be a "beneficial owner" of a security if that person has or shares the power to dispose or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which the person has the right to acquire beneficial ownership within 60 days pursuant to options, warrants, conversion privileges or similar rights. Unless otherwise indicated, ownership information is as of March 15, 2018, and is based on 3,923,027 shares of common stock outstanding on that date.

Name of Beneficial Owner(1)	Number of Shares Beneficially Owned	Percentage Owned (%)
Francois Michelin	163,299(2)	4.0%
Michael Thornton	205,558(3)	5.1%
David R. Wells	30,833(4)	*
Dr. Sanjiv Sam Gambhir	28,832(5)	*
Michael Harsh	17,371(6)	*
Alexander Tokman	21,170(7)	*
Anthony DiGiandomenico	76,720(8)	1.9%
All directors and named executive officers as a group (7 individuals)	546,780	12.7%
<i>5% or More Shareholders</i>		
Longboard Capital Advisors, LLC	652,463(9)	15.7%

- (1) The address of each officer and director is 3600 Green Court, Suite 350, Ann Arbor, MI 48105-1570.
- (2) Consists of 26,544 shares of common stock and 136,755 shares of common stock issuable upon the exercise of options that are presently exercisable.
- (3) Consists of 59,998 shares of common stock, 144,570 shares of common stock issuable upon the exercise of options that are presently exercisable and 999 shares of common stock issuable upon the exercise of restricted warrants.
- (4) Consists of 18,833 shares of common stock and 12,000 shares of common stock issuable upon the exercise of options that are presently exercisable.
- (5) Consists of 28,832 shares of common stock issuable upon the exercise of options that are presently exercisable.
- (6) Consists of 17,371 shares of common stock issuable upon the exercise of options that are presently exercisable.

- (7) Consists of 21,170 shares of common stock issuable upon the exercise of options that are presently exercisable.
- (8) Consists of 58,625 shares of common stock, 17,096 shares of common stock issuable upon the exercise of options that are presently exercisable and 999 shares of common stock issuable upon the exercise of restricted warrants.
- (9) Based solely on the Schedule 13G filed on July 13, 2017 by Longboard Capital Advisors, LLC (“Longboard”) and Brett Conrad. According to the filing, shares consist of 429,437 shares of common stock and 223,026 shares of common stock issuable upon the exercise of warrants owned by Longboard. Mr. Conrad is the managing member of Longboard and has the power to make voting and investment decisions regarding the shares of common stock and warrants held by Longboard. The address for this investor is 1312 Cedar Street, Santa Monica, CA 90405.

Equity Compensation Plan Table

The following table presents information on the Company’s equity compensation plans as of December 31, 2017. All outstanding awards relate to our common stock.

Plan Category	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted- Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	940,121(1)	\$ 5.65	404,953(2)
Equity compensation plans not approved by security holders	—	—	—
Total	940,121	\$ 5.65	404,953

(1) Consists of outstanding stock options exercisable for 940,121 shares of common stock issued under our 2016 Omnibus Incentive Plan, which amended and restated our Second Amended and Restated 2013 Stock Incentive Plan.

(2) Consists of 404,953 shares of common stock available for future issuance under our 2016 Omnibus Incentive Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Policy for Review of Related Person Transactions

In December 2016, our board of directors adopted a written policy with regard to related person transactions, which sets forth our procedures and standards for the review, approval or ratification of any transaction required to be reported in our filings with the SEC or in which one of our executive officers or directors has a direct or indirect material financial interest, with limited exceptions. Our policy is that the Corporate Governance and Nominating Committee shall review the material facts of all related person transactions (as defined in the related person transaction approval policy) and either approve or disapprove of the entry into any related person transaction. In the event that obtaining the advance approval of the Corporate Governance and Nominating Committee is not feasible, the Corporate Governance and Nominating Committee shall consider the related person transaction and, if the Corporate Governance and Nominating Committee determines it to be appropriate, may ratify the related person transaction. In determining whether to approve or ratify a related person transaction, the Corporate Governance and Nominating Committee will take into account, among other factors it deems appropriate, whether the related person transaction is on terms comparable to those available from an unaffiliated third-party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

Related Person Transactions

SEC regulations define the related person transactions that require disclosure to include any transaction, arrangement or relationship in which the amount involved exceeds the lesser of \$120,000 or one percent of the average of the Company’s total assets at year end for the last two completed fiscal years in which we were or are to be a participant and in which a related person had or will have a direct or indirect material interest. A related person is: (i) an executive officer, director or director nominee of the Company, (ii) a beneficial owner of more than 5% of our common stock, (iii) an immediate family member of an executive officer, director or director nominee or beneficial owner of more than 5% of our common stock, or (iv) any entity that is owned or controlled by any of the foregoing persons or in which any of the foregoing persons has a substantial ownership interest or control.

For the period from January 1, 2016 through December 31, 2017 (the “Reporting Period”), described below are certain transactions or series of transactions between us and certain related persons.

On January 28, 2016, we issued convertible promissory notes to Sanjiv Gambhir (the “Gambhir Note”), Michael Harsh (the “Harsh Note”) and Alexander Tokman (the “Tokman Note”), each a member of our board of directors. The Gambhir Note and the Tokman Note are each in the principal sum of \$20,000 and the Harsh Note is in the principal sum of \$10,000. None of the notes accrue interest and all three are payable upon the earlier of (1) completion by the Company of an equity financing of \$4.0 million or more and (2) the one-year anniversary of the issuance date. All outstanding amounts due under the Harsh Note, Tokman Note and Gambhir Note were paid in full on May 15, 2017.

From April 2016 through March 2017, we issued convertible promissory notes to the following related persons: (i) Francois Michelin, our Chief Executive Officer, in the principal sum of \$35,000, (ii) Michael Thornton, our Chief Technology Officer, in the principal sum of \$52,000, (iii) Anthony DiGiandomenico, a director of the Company, in the principal sum of \$25,000, (iv) a trust beneficially owned by Robert C. Clifford, a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sum of \$19,474, (v) a trust beneficially owned by Daniel Landry, a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sum of \$25,000, (vi) Benjamin L. Padnos, a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sums of \$35,000, \$54,500 and \$100,000, (vii) Cynthia Padnos, an immediate family member of a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sum of \$12,096, (viii) Daniel Padnos, an immediate family member of a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sums of \$7,258 and \$25,000, (ix) Jeffrey S. Padnos and Margaret M. Padnos (including trusts which they beneficially own), joint beneficial owners of more than 5% of our common stock at the time of the transaction, in the principal sums of \$25,000 and \$96,811, (x) Jonathan Padnos, an immediate family member of a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sums of \$17,258 and \$25,000, (xi) Sivan Padnos Caspi, an immediate family member of a beneficial owner of more than 5% of our common stock at the time of the transaction, in the principal sum of \$7,258, (xii) Michael Thornton, our Chief Technology Officer, in the principal sum of \$20,000, and (xiii) Conal Thornton, the father of Michael Thornton, our Chief Technology Officer, in the principal sum of \$20,000. Each such note accrued interest at the rate of 8% per annum and was secured by all assets of the Company. Upon the election of noteholders holding a majority of the outstanding principal amount of the convertible promissory notes, all outstanding convertible promissory notes were convertible into shares of the Company's common stock, in each case at a conversion price of \$1.40 per share. Pursuant to such terms, the noteholders elected to convert all of the outstanding principal and accrued interest on the convertible promissory notes into an aggregate of 1,232,859 shares of common stock of the Company on May 12, 2017, immediately prior to the completion of our initial public offering.

Director Independence

We have listed our common stock and warrants on the Nasdaq Capital Market, therefore, our determination of the independence of directors is made using the definition of "independent" contained in the listing standards of the Nasdaq Stock Market. On the basis of information solicited from each director, our board of directors has determined that each of Anthony DiGiandomenico, Dr. Sanjiv Sam Gambhir, Michael Harsh and Alexander Tokman is independent within the meaning of such rules.

Item 14. Principal Accountant Fees and Services

RBSM LLP ("RBSM") audited our financial statements for the year ended December 31, 2017. The following table sets forth the aggregate fees billed or expected to be billed by RBSM for audit and non-audit services in 2017 and 2016, including "out-of-pocket" expenses incurred in rendering these services. The nature of the services provided for each category is described following the table.

Fees	2017	2016
Audit Fees (1)	\$ 118,500	\$ 50,000
Audit Related Fees	-	-
Tax Fees	5,000	-
Total	\$ 123,500	\$ 50,000

(1) Audit fees include fees for professional services rendered for the audit of our annual statements, quarterly reviews, consents and assistance with and review of documents filed with the SEC.

Pre-Approval Policies and Procedures

The Audit Committee of our board of directors has adopted a policy that requires that all services to be provided by the Company's independent public accounting firm, including audit services and permitted non-audit services, to be pre-approved by the Audit Committee. All audit and permitted non-audit services provided by RBSM during 2017 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits, Financial Statements and Schedules

(a) List of documents filed as part of this report:

1. Financial Statements (see "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference)
2. Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto)
3. Exhibits

The following is a list of exhibits filed as part of this Annual Report:

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Filed Herewith	Form	Exhibit	Filing Date
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant		8-K	3.2	05/12/17
3.2	Amended and Restated Bylaws of the Registrant		S-1	3.4	11/21/16
4.1	Specimen Certificate representing shares of common stock of the Registrant		S-1	4.1	11/21/16
4.2	Form of Warrant Agreement and Warrant comprising a part of the Registrant's units issued in its 2017 initial public offering		S-1	4.2	11/21/16
4.3	Form of Underwriters' Warrant issued to certain designees of the underwriters in the Registrant's 2017 initial public offering		S-1	4.3	11/21/16
4.4	Form of Convertible Promissory Note		S-1	4.8	11/21/16
10.1	ENDRA Life Sciences Inc. 2016 Omnibus Incentive Plan *		S-1	10.4	12/06/16
10.2	Form of Stock Option Award under 2016 Omnibus Incentive Plan*		S-1	10.5	12/06/16
10.3	Form of Restricted Stock Unit Award under 2016 Omnibus Incentive Plan*		S-1	10.6	12/06/16
10.4	Non-Employee Director Compensation Policy*		S-1	10.7	01/20/17

10.5	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers*	S-1	10.8	11/21/16	
10.6	Amended and Restated Employment Agreement, dated May 12, 2017, by and between the Registrant and Francois Michelin*	8-K	10.1	05/12/17	
10.7	Amended and Restated Employment Agreement, dated May 12, 2017, by and between the Company and Michael Thornton*	8-K	10.2	05/12/17	
10.8	Consulting Agreement, dated May 12, 2017, by and between the Company and StoryCorp Consulting*	8-K	10.3	05/12/17	
10.9	Collaborative Research Agreement, dated April 22, 2016, by and between the Registrant and General Electric Company	S-1	10.17	11/21/16	
10.10	Amendment to Collaborative Research Agreement, dated April 21, 2017, by and between the Registrant and General Electric Company	S-1	10.21	05/03/17	
10.11	Amendment 2 to Collaborative Research Agreement, dated January 30, 2018, by and between the Registrant and General Electric Company	8-K	10.1	01/30/18	
10.12	Gross Lease, dated January 1, 2015, between the Registrant and Green Court LLC	S-1	10.18	11/21/16	
10.13	Sublicense Agreement, dated August 2, 2007, by and between the Registrant and Optosonics, Inc.	S-1	10.19	11/21/16	
10.14	Amendment to Sublicense Agreement, dated January 18, 2011, by and between the Registrant and Optosonics, Inc.	S-1	10.20	11/21/16	
10.15	Master Services Agreement, dated October 24, 2017, by and between the Registrant and CriTech Research, Inc.				X
10.16	Consulting Agreement, dated October 31, 2017, by and between the Registrant and StarFish Product Engineering, Inc.				X
21.1	Subsidiaries of the Registrant				X
23.1	Consent of RBSM LLP, Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (included on signature page)				X
31.1	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934				X
31.2	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934				X
32.1	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Schema				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase				X
101.LAB	XBRL Taxonomy Extension Label Linkbase				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase				X

* Indicates management compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ENDRA Life Sciences Inc.

Dated: March 20, 2018

By: /s/ Francois Michelin
Francois Michelin
Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of ENDRA Life Sciences Inc., hereby severally constitute and appoint Francois Michelin our true and lawful attorney, with full power to him to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable ENDRA Life Sciences Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities Exchange Commission.

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

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Francois Michelin</u> Francois Michelin	Chief Executive Officer and Director (Principal Executive Officer)	March 20, 2018
<u>/s/ David R. Wells</u> David R. Wells	Chief Financial Officer (Principal Financial and Accounting Officer)	March 20, 2018
<u>/s/ Anthony DiGiandomenico</u> Anthony DiGiandomenico	Director	March 20, 2018
<u>/s/ Sanjiv Gambhir, M.D., Ph.D.</u> Sanjiv Gambhir, M.D., Ph.D.	Director	March 20, 2018
<u>/s/ Michael Harsh</u> Michael Harsh	Director	March 20, 2018
<u>/s/ Alexander Tokman</u> Alexander Tokman	Director	March 20, 2018

MASTER SERVICES AGREEMENT

AGREEMENT, made and entered into this 24th day of October, 2017 (the "EFFECTIVE DATE"), by and between CRITECH RESEARCH, INC., a Michigan corporation, whose address is 1705 Woodland Drive East, Suite 100, Saline, Michigan 48176 ("CRITECH"), and ENDRA Life Sciences, whose address is 3600 Green Court, Suite 350, Ann Arbor, MI 48105 ("CLIENT").

RECITALS:

- A. CLIENT desires to retain CRITECH to perform services on its behalf.
- B. CRITECH is engaged in the business of developing computer programs that have medical applications and has agreed to assist CLIENT, upon the terms and conditions set forth in this Agreement.

NOW, THEREFORE, the parties agree as follows:

1. **Scope of Work.** CLIENT may issue mutually acceptable PROJECT ASSIGNMENTS to CRITECH in the form attached to this Agreement as Exhibit A ("PROJECT ASSIGNMENT"). Subject to the terms of this Agreement and to CLIENT fulfilling its performance obligations under any PROJECT ASSIGNMENT, CRITECH will use commercially reasonable efforts in rendering the services set forth in the PROJECT ASSIGNMENT(S) by the completion dates set forth therein.
2. **Compensation.** CLIENT will pay CRITECH the mutually agreed upon fee set forth in each PROJECT ASSIGNMENT for services rendered pursuant to this Agreement. CRITECH will charge CLIENT for reimbursable costs, including any travel and material expenses, which are expressly provided for in a PROJECT ASSIGNMENT or which have been approved in advance in writing by an authorized CLIENT representative.

All charges for personnel time shall be on a straight time basis, regardless of the number of hours worked by any employee on any one day or during any one week, and regardless of the day on which services are performed. CRITECH shall invoice CLIENT monthly for work performed and reimbursable expenses under the PROJECT ASSIGNMENT(S). CLIENT shall pay that invoice on a NET 15 basis.

3. **Term.** This Agreement is effective as of the Effective Date set forth above and will remain in effect for an indefinite term until terminated as set forth below. CRITECH shall begin performing services under this Agreement when the first mutually agreeable PROJECT ASSIGNMENT is executed.
4. **CLIENT's Efforts.** In connection with any PROJECT ASSIGNMENT(S) accepted by CRITECH, CLIENT agrees to reasonably cause; (i) CLIENT's appropriate engineers and other personnel to interface with CRITECH's engineers and personnel as anticipated in the PROJECT ASSIGNMENT and as reasonably necessary to enable CRITECH to perform its duties under this Agreement; (ii) access to be given to CRITECH to all relevant written documentation and source code pertaining to the product and its software; (iii) the availability of appropriate meeting areas; and (iv) the availability of appropriate work areas (including desk and telephone access) for CRITECH's engineering efforts that are to occur on site at CLIENT's premises.
5. **Termination.** Either party may terminate this Agreement at any time for any reason upon written, fifteen (15) day notice to the other party. After receiving a notice of early termination, CRITECH shall invoice CLIENT for all services performed and reimbursable expenses incurred through the effective date of termination (including the notice period) and CLIENT shall pay that invoice on a NET 15 basis. CRITECH will use reasonable efforts to minimize the amount of any work performed or expenses incurred after receiving a notice of early termination. Upon any termination of this Agreement, CRITECH shall assist, at CLIENT'S request and expense, with the transfer of the PROJECT ASSIGNMENT(S) to another party in order to minimize any delay caused by such termination.

CRITECH reserves the right to suspend the performance of services if CLIENT defaults in making any of the payments due to CRITECH under this Agreement.

6. **Title.** CLIENT shall be the sole owner of the work products and deliverables produced specifically for CLIENT under this Agreement, including source code, resulting object code, and documentation ("DELIVERABLES"). All DELIVERABLES shall be considered work made for hire, as defined in 17 U.S.C. §101. To the extent that any of the DELIVERABLES do not constitute a work made for hire, CRITECH hereby irrevocably assigns to CLIENT, without additional consideration, all right, title, and interest in and to the DELIVERABLES, including all intellectual property rights therein. CRITECH shall execute any additional documentation as CLIENT may reasonably request, and at CLIENT's expense, to confirm CLIENT's sole ownership of the work products and deliverables. Any intellectual property developed or created by CRITECH, prior to the EFFECTIVE DATE ("PRE-EXISTING IP"), shall remain the property of CRITECH and with respect to which, CRITECH hereby grants to CLIENT a nonexclusive, perpetual, irrevocable, royalty-free, sublicensable, transferable, and worldwide license to use, perform, display, execute, reproduce, distribute, transmit, modify (including to create derivative works), import, make, have made, sell, offer to sell and otherwise exploit such PRE-EXISTING IP to the extent incorporated in, combined with, or otherwise necessary for the use of the DELIVERABLES. Subject only to the foregoing license, all rights, title and interest in and to the PRE-EXISTING IP shall remain vested in CRITECH.

CRITECH agrees to notify CLIENT and to receive advance approval in writing from CLIENT for the incorporation of PRE-EXISTING IP into DELIVERABLES.

7. **Warranties.** CRITECH represents and warrants to CLIENT that CRITECH will be the sole author of any software developed under this Agreement. All work on software will either be CRITECH's original work or will include the work of others which has been lawfully obtained by CRITECH and legitimately transferred to CLIENT. None of such work shall infringe upon a valid United States Patent or Copyright. **BECAUSE OF THE LIMITED NATURE OF CRITECH'S SERVICES HEREUNDER, CRITECH DISCLAIMS ALL OTHER WARRANTIES REGARDING THE SOFTWARE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.** Following verification, validation and acceptance testing by CRITECH of work product and deliverables under this Agreement and ENDRA's review of such testing results and acceptance thereof, CLIENT shall be responsible for performing system integration of the work products and deliverables. CLIENT shall be solely responsible for the performance of the work products and deliverables following delivery and CLIENT'S acceptance thereof. Each party shall indemnify, defend and hold the other party harmless with respect to any successfully asserted third party claim, demand, cause of action, debt or liability to the extent that such claim arises out of its own (i) grossly negligent acts; (ii) grossly negligent omissions, (iii) willful misconduct, (iv) breach of any provision of this Agreement or (v) violation of law.
8. **Limitation of Liability.** CRITECH SHALL NOT BE RESPONSIBLE TO CLIENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS THAT MAY ARISE OUT OF THIS AGREEMENT OR ANY ALLEGED FAILURE BY CRITECH TO PERFORM ITS DUTIES UNDER THIS AGREEMENT EVEN IF CRITECH WERE MADE AWARE OF THE POSSIBILITY OF SUCH DAMAGES. CRITECH'S LIABILITY FOR DAMAGES UNDER THIS AGREEMENT SHALL BE LIMITED TO THE LESSER OF THE ACTUAL DAMAGES SUFFERED BY CLIENT OR THE TOTAL AMOUNT PAID TO CRITECH HEREUNDER FOR THE PROJECT ASSIGNMENT. No action, except for a claim for indemnity by CRITECH under Section 7 hereof, may be brought by one party against the other with regard to services performed by CRITECH under this Agreement more than two (2) years after the earlier of the effective date of termination of this Agreement or the completion date of the PROJECT ASSIGNMENT out of which that action arises.
9. **Non-Disclosure.** The terms of the Non-Disclosure/Confidentiality Agreement executed by CRITECH and by CLIENT on _4 August 2017_ shall remain in effect following the execution of this Agreement.
10. **CLIENT Property.** Neither CRITECH nor any person shall use for their benefit, or for the benefit of any person or entity other than CLIENT, any information, data, equipment or supplies that are the property of CLIENT.
11. **Independent Contractor.** The relationship of the parties shall be that of principal and independent contractor. The parties intend no employment, joint venture or agency relationship to result from their entry into and performance of services under this Agreement. Neither party shall have the authority to bind or obligate the other in any manner whatsoever. Neither party shall be responsible for an act or omission of the other or any employee of the other. CRITECH shall be responsible for reporting and paying all taxes that are due by it with regard to compensation received by it pursuant to this Agreement. CRITECH shall also be solely responsible for providing the facilities from which its services will be performed and for bearing all expenses associated with the performance of its service, except for obtaining reimbursement of those expenses described as "reimbursable expenses" in the PROJECT ASSIGNMENT(S). Any reimbursement will not exceed amounts allocated for such expenses on CLIENT's PROJECT ASSIGNMENT(S). CRITECH shall be solely responsible for compensating and supervising its employees and agents, CRITECH shall maintain in effect such written agreements with its employees, agents and contractors as necessary for CRITECH to comply with the provisions of this Agreement.
12. **Default.** A party shall be in default under this Agreement if it does not cure any breach or failure of performance within thirty (30) days after receiving written notice of default from the non-defaulting party. Any such written notice shall describe the condition of default in reasonable detail.
13. **Survival of Covenants.** In the event that CRITECH sells its medical software development business or otherwise transfers, reorganizes or restructures that portion of its business that pertains to the development of medical software, CRITECH shall transfer to the person or entity that acquires CRITECH's medical software development business all of CRITECH's rights, obligations and benefits under this Agreement. Any such transfer shall be effective only upon the prior written consent of CLIENT. After effecting such a transfer, CRITECH shall cooperate with CLIENT and the transferee in assuring a smooth transition in the performance of services under this Agreement, all with a view toward causing the services to be completed within the time frame and in accordance with the PROJECT ASSIGNMENT(S).
14. **Confidential Information.** The terms of this Section 14 are of a continuing nature and shall survive the termination of this Agreement in perpetuity except as provided herein. Each party acknowledges that in the course of performance of its respective obligations under this Agreement, it may obtain Confidential Information of the other party or its affiliates. Each party agrees, for itself and on behalf of its personnel, directors, agents and advisors, that Confidential Information will remain the property of and be returned to the disclosing party (along with all copies thereof) within thirty (30) days of the termination of the Agreement, and to hold in confidence and to not disclose to any third party any Confidential Information; provided that the recipient of such information shall have no confidentiality obligation to the extent that the disclosed information is (or becomes):
 - (a) published by a third party in generally available media other than as a result of the improper action of a receiving Party;
 - (b) generally available to the public other than as a result of the improper action of a receiving Party;

(c) known from a source independent of any confidentiality restrictions; or

(d) developed independently by a receiving Party without reliance upon the other Party's Confidential Information or intellectual property rights (including, without limitation, any continuing rights to derivative works), provided that any such claim of independent development by a receiving Party must be supported by written and dated records that substantiate such claim of independent development.

For purposes of this Agreement, "Confidential Information" shall mean information that is designated by a providing party as confidential, or that should reasonably be understood by a receiving party to be confidential or proprietary under the circumstances, whether or not such information is marked or identified as "confidential" by the disclosing party. Confidential Information includes, without exclusion, proprietary materials, technology, know-how, procedures, processes, protocols, specifications, strategic plans, designs, systems, software object code and source code, documentation, sales and marketing plans, results of testing, customer information, financial information, product information, proposed business arrangements, methods of operation and compilations of data.

14. **Employee Non-Solicitation.** For so long as this Agreement is in effect and for two (2) years thereafter;

- (a) neither party shall solicit for employment any person who is or who becomes an employee of the other party at any time that this Agreement is in effect;
- (b) neither party shall induce any employee of the other party to terminate his/her employment; and
- (c) neither party shall solicit for employment any person who was an employee of the other party for a period of six (6) months following the employee's termination of employment with the other party.

Notwithstanding the foregoing, nothing in this Section 14 shall restrict (i) either party from employing any person who seeks such employment of his own accord, or (ii) the making of any general, non-targeted advertisements or solicitations for employment by any party.

15. **Export.** CLIENT shall have the sole right to control export of the software. CLIENT shall be responsible for complying with all laws and regulations applicable to any export of the software.

16. **Notice.** Any and all notices, or any other communication provided for herein, shall be given in writing by registered or certified mail, return receipt requested, and shall be addressed to:

CLIENT: Attn. (NAME/DEPT)
CLIENT
ADDRESS

CRITECH: Robert J. Rajewski
CriTech Research, Inc.
1705 Woodland Drive East, Suite 100
Saline, MI 48176

A notice shall be effective on the date of receipt.

17. **Benefit.** This Agreement shall be binding upon the parties, and upon their heirs, administrators, executors, successors and permitted assigns. Further, the parties agree to execute any additional instruments which may be necessary or proper to carry out the intents and purposes of this Agreement.

18. **Entire Agreement.** This Agreement constitutes the entire understanding of the parties with respect to the subject matter hereof and supersedes entirely any prior written or oral agreements.

19. **Modification.** No change or modification of this Agreement shall be valid unless the same is in writing and signed by all of the parties.

20. **Waiver.** The failure by a party to this Agreement to enforce any covenant hereof or to seek any remedy available hereunder following a noncompliance with or a breach of this Agreement shall not operate as a waiver of such covenant or remedy either as to the first or any subsequent noncompliance or breach.
21. **Headings.** The headings contained in this Agreement have been added for convenience only and shall not be construed as limiting.
22. **Arbitration; Injunctive Relief.** Except for the injunctive relief allowed by the Non-Disclosure/Confidentiality Agreement referred to in Section 9, and the right to file a third party action for indemnity or otherwise in a litigation filed by others, any controversy or claim arising out of, or relating to this Agreement or the breach hereof, or of the interpretation hereof, shall be settled by arbitration in accordance with the Rules of the American Arbitration Association; and judgment on the award rendered in such arbitration shall be final and may be entered in any court having jurisdiction thereof. The arbitration hearing shall take place in Ann Arbor, Michigan. The arbitrator shall be entitled to award reasonable attorney's fees and expenses to the prevailing party. In no event shall the demand for arbitration be made after the date when institution of legal or equitable proceedings based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations except, if a party has filed a court action within the period allowed by the applicable statute of limitations, that party may file a demand for arbitration as to some or all of the claims of that action if requested to do so by the other party or ordered to do so by a court, and the opposing party may file a demand for arbitration with respect to some or all of the claims of that action, as otherwise permitted by law or ordered by a court. This agreement to arbitrate shall be specifically enforceable under the prevailing arbitration law.
23. **Invalid Provision.** The invalidity or unenforceability of any particular provision of this Agreement shall not affect the other provisions hereof, and the invalid or unenforceable provision shall be given effect to the extent permitted by law.
24. **Governing Law.** The validity, performance and construction of this Agreement shall be governed by the laws of the State of Michigan. Jurisdiction and venue for any litigation that arises out of this Agreement shall be in state courts in Washtenaw County, Michigan, or in Federal District Court for the Eastern District of Michigan.
25. **Publicity.** Neither Party may issue press releases or make additional information regarding the business relationship between the Parties publicly available unless is shall have first obtained the consent of the other Party.

IN WITNESS WHEREOF, the parties have signed this Agreement on the day and year first above written.

CRITECH RESEARCH, INC.

ENDRA LIFE SCIENCES

By: /s/ Robert J. Rajewski

By: /s/Francois Michelon

Robert J. Rajewski

Francois Michelon

Its: President

Its: CEO

Date:24 October 2017

Date:24 October 2017

Exhibit A

PROJECT ASSIGNMENTS

CRITECH RESEARCH INC.

Document
CRI-CCNNN-PA-0100

Page 1 of 6
<<Baseline Date>>

CLIENT

<<Project Name>>

Project Assignment

CriTech Research, Inc
Copyright © 2002

Contact
<<AUTHOR>>
CriTech Research, Inc.
1705 Woodland Drive East, Suite 100
Saline, Michigan 48176
734-668-0005

Approvals

CRITECH RESEARCH, INC.

Client

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EXECUTIVE SUMMARY

CriTech Research proposes to perform a <<Project Name>> for CLIENT.

CriTech Research proposes to perform the following tasks using an IEEE compliant process:

1. Description of the tasks to be performed

The effort is estimated to have an N-month duration, with a start date agreed upon by CriTech Research and CLIENT. The project has an estimated total cost of **\$TBD**. The estimate includes \$TBD for the cost of travel for one to two engineers monthly to CLIENT for status and issue meetings .

CLIENT shall provide engineers and domain experts to provide information during the project in order for CriTech to create the best possible product.

This proposal is effective for fifteen days from the date on the cover sheet. After that time, CriTech Research reserves the right to re-plan and re-quote the activity based upon available staffing.

PROPOSAL SCOPE

TASK DESCRIPTIONS

The "<<Project Name>> - Statement of Work", CRI-CCNNN-SOW-0100, dated DD MONTH YYYY, provides a detailed list of the specific tasks to be performed as part of the effort.

DELIVERABLES

The "<<Project Name>> - Statement of Work", CRI-CCNNN-SOW-0100, dated DD MONTH YYYY, provides a detailed list of the specific deliverables to be developed as part of the effort.

CriTech Research shall deliver one copy of each of the deliverables. Further replication of the deliverables shall be the responsibility of CLIENT. Each of the items will be delivered in hard copy and electronic copy, where possible.

MILESTONES

CriTech Research estimates the following milestones for this effort:

Milestone	Responsibility
Project start	CriTech/Client
Deliver PMP	CriTech
Status Reports (weekly)	CriTech
Teleconferences (weekly)	CriTech/Client
Project Deliverables (TBD)	CriTech
Project completed	CriTech/Client

CriTech Research will provide periodic schedule updates and estimates to complete the effort.

LINE ITEMS

CriTech Research recommends the following line items be placed on the Purchase Order:

Line Item	Hours	Rates	Cost
Labor			
Software Engineer	staff-hours	\$TBD per hour	\$ TBD
Travel & Materials	N/A	At Cost	\$ TBD
	Total	TBD man-hours	\$ TBD

START WORK CONDITIONS

CriTech Research will start work under the following conditions:

RISKS

Initial risk analysis has been completed for this program. Table 1.0 provides a summary of the technical and schedule risks, which have been identified at this point in the planning process.

	RISK DESCRIPTION	POSSIBLE CAUSES	PREVENTATIVE ACTIONS	CONTINGENCY PLANS	PRIORITY
1.	TBD	TBD	TBD	TBD	TBD

Table 1.0 Risk Summary

General Assumptions

The following assumptions are included in this estimate:

CONSTRAINTS

TBD

FACILITIES/RESOURCES

CRITECH RESEARCH

CriTech Research shall provide the following facilities for the duration of this activity:

1. TBD

CUSTOMER

CLIENT shall provide the following resources for this activity:

1. TBD

Revision History

VERSION NUMBER	DATE	WHO	COMMENTS
CRI-CCNNN-PA-0100	DD MONTH YYYY	TBD	ORIGINAL RELEASE

CONSULTING AGREEMENT

October 31, 2017

BETWEEN:

StarFish Product Engineering, Inc.
(hereinafter referred to as "StarFish")

AND:

ENDRA LIFE SCIENCES, CANADA, INC.
(Hereinafter referred to as **ENDRA**)

IN CONSIDERATION of the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. SERVICES

- a) ENDRA has retained StarFish to proceed with SOW 1 as outlined in the accepted proposal 36829 – X6 dated October 13, 2017] (the "**SOW**") attached hereto as Schedule A. From time to time, the parties may execute additional statements of work. Upon execution, unless otherwise expressly agreed, each such additional statement of work shall be deemed to form a part of and be subject to the terms of this Agreement. In case of any inconsistency between the terms contained in the main body of this Agreement and the terms contained in any statement of work, the terms contained in the main body of this Agreement shall prevail unless expressly stated otherwise in the relevant statement of work.
- b) StarFish will use commercially reasonable efforts to perform the services ("**Services**") and deliver any resulting Deliverables described in the SOW and any subsequent statement of work, in accordance with the terms of this Agreement. StarFish represents and warrants that all Services will be performed in a professional and workmanlike manner, in accordance with generally accepted industry standards, and by individuals who are duly qualified and possess the requisite skills and professional knowledge.

2. PAYMENT TERMS

- a) Fees and other compensation to be paid for any work will be as agreed in the relevant statement of work. The price for the Services will not include any applicable taxes and expenses. Those Services performed on a time and materials basis will be provided at the prevailing StarFish corporate rates.
- b) A deposit shall be required prior to commencement of the Services and will be as agreed in the relevant statement of work. The timeline for the performance of the Services, delivery of any Deliverables and invoicing schedule shall be agreed to as set out in the statement of work. StarFish will invoice ENDRA for all payments.
- c) ENDRA will be liable for all taxes, duties and levies (“**Taxes**”) applicable to the supply of the Services and any Deliverables, other than taxes on StarFish’s income. All applicable Taxes shall be clearly identified as listed as separate line items on each invoice.
- d) Expenses will be invoiced to ENDRA, at the end of each invoice period in which the costs were incurred, plus a mark-up of 15% for handling. Invoices shall be reasonably detailed such that the amount of payments for engineering, design, research, analysis, computer programming and data collection activities, collectively, are identifiable. Written approval of parts purchases will be required from ENDRA prior to StarFish purchasing these parts. StarFish may require an additional deposit to cover all or part of any expenses before the expenses are incurred.
- e) Following completion of the Services, late-arriving expense and shipping charges will be invoiced once received. This can vary significantly after completion of the Services. ENDRA understands and agrees that a portion of the deposit will be retained until these charges have been paid.
- f) Unless otherwise expressly stated, all references to monetary amounts contained in this Agreement, or any in statement of work, purchase orders or invoices issued pursuant to this Agreement, shall be deemed to be references to United States dollars.
- g) Payment terms for the Services are NET 30 days from date of invoice. Deposits are due as of the date of invoice. Interest of 1.5% per month (19.6% per annum) will be payable to StarFish on any overdue invoices.
- h) Without limiting any other remedies that it may have in contract, at law or in equity, ENDRA acknowledges and agrees that in the event that ENDRA fails to make any payments when due, or is otherwise in material breach of this Agreement, StarFish may at its discretion, and without liability, suspend performance of the Services until any outstanding payments have been received. All timelines and associated delivery dates shall be deemed to have been adjusted accordingly.

3. INDEPENDENT CONTRACTORS

- a) The parties are independent contractors, and neither party's employees, agents, or consultants shall be considered or identified as employees, agents or consultants of the other party for any purpose whatsoever. Neither party will have the authority to bind or act as the agent for the other party.
- b) StarFish acknowledges that ENDRA has no obligation to offer employees, agents, or consultants of StarFish any form of health benefits program or any other form of compensation. StarFish will be solely responsible for payment to the proper authorities of all income taxes, employment insurance, and other premiums, contributions, withholdings and remittances relating to its employees' performance of the Services.
- c) Nothing contained herein shall prevent either party from procuring or providing the same or similar products and services from or to any third party, provided that there is no breach of any obligations pertaining to confidentiality or the use and protection of intellectual property.

4. INTELLECTUAL PROPERTY RIGHTS

- a) StarFish agrees to promptly disclose and deliver to ENDRA all information, inventions, creations, improvements, materials, items, source code, object code, products or data developed by StarFish pursuant to the Services ("**Deliverables**").
- b) Subject to the payment of all undisputed amounts owing in respect of the Services, StarFish hereby irrevocably conveys and assigns to ENDRA all of StarFish's rights, title and interest in and to all Deliverables, effective as of the date that each is created, including all copyrights, data rights, patents (including patent registration application and extensions), know-how, trade secrets, trademark, service marks and any other proprietary right arising under the laws of Canada, the United States, or any other jurisdiction or treaty (collectively, "**IP Rights**"). Subject to Section 4(c), all Deliverables will be the sole and exclusive property of ENDRA. ENDRA has the sole right to determine the treatment of any portion of the Deliverables, including the right to keep it as a trade secret, to file and execute patent applications on it, to use and disclose it without prior patent applications or to follow any other procedure that ENDRA deems appropriate. StarFish represents and warrants that ENDRA will receive good and valid title to all Deliverables, that all Deliverables will be, to StarFish's actual knowledge, free and clear of all encumbrances and liens of any kind, and that all Deliverables are or will be the original creation of StarFish.
- c) To the extent that any Deliverables contain any pre-existing StarFish intellectual property ("**Pre-Existing IP**"), StarFish grants to ENDRA a perpetual, non-exclusive, royalty-free, irrevocable, sublicensable, transferrable, and worldwide right and license to use, perform, display, execute, reproduce, distribute, transmit, modify (including to create derivative works), import, make, have made, sell, offer to sell and otherwise exploit such Pre-Existing IP to the extent incorporated in, combined with, or otherwise necessary for the use of the Deliverables. StarFish shall identify in writing, and receive advance approval in writing of, the incorporation of any such Pre-Existing IP into any Deliverables to ENDRA. Subject only to the foregoing license, all rights, title and interest in and to the Pre-Existing IP shall remain vested in StarFish. StarFish represents and warrants that all Pre-Existing IP has been lawfully obtained by StarFish and will be legitimately transferred to ENDRA.
- d) StarFish shall in good faith cooperate with and assist ENDRA, at ENDRA 's expense, to apply for and execute any documents or otherwise take any such steps as are necessary to perfect and obtain ENDRA's world-wide ownership of its IP Rights in the Deliverables as described in Sections 4(b) and 4(c). StarFish acknowledges that all Deliverables will be ENDRA's Confidential Information and StarFish shall treat all Deliverables as such under this Agreement.

- e) StarFish hereby expressly waives, and shall ensure that its personnel waive, any moral rights in the Deliverables, including, without limitation, the right to the integrity of the Deliverables, the right to be associated with the Deliverables, the right to restrain or claim damages for any distortion, mutilation or other modification of the Deliverables, and the right to restrain the use or reproduction of the Deliverables in any context and in connection with any product, service, cause or institution, effective at the time the particular Deliverable is created.
- f) In the event that StarFish delivers to ENDRA, as part of the Deliverables, any compiled, StarFish proprietary software libraries, such proprietary software libraries shall be considered Pre-Existing IP and subject to the rights and license set forth in Section 4(c). For greater certainty, except for the limited rights and license to use such proprietary software libraries in conjunction with the Deliverables as provided in Section 4(c), all rights, title and interest in and to such StarFish software remain vested in StarFish.
- g) StarFish represents and warrants that the Services, Deliverables, Pre-Existing IP will not infringe, misappropriate, or otherwise violate any intellectual property rights of any third party to StarFish's actual knowledge. Except as expressly provided herein, the Services, Deliverables, Pre-Existing IP and any StarFish software are provided "as is" without warranties of any kind, whether express, implied or statutory, including but not limited to warranties of merchantability, fitness for a particular purpose or non-infringement, all of which are expressly excluded.

5. NON-SOLICITATION

- a) The parties covenant and agree that they will not, directly or indirectly, during the Term of this Agreement and for a period of one year following the effective date of the termination of this Agreement,
 - i) be a party to or abet any solicitation of customers, clients or suppliers of the other party, to transfer business from the other party to it or to any other person or entity; or
 - ii) seek in any way to persuade or entice any employee of the other party to leave that employ, or be a party to or abet any such action; provided, that the foregoing shall not restrict (i) the employment of any employee who seeks such employment of his own accord, or (ii) the making of any general non-targeted advertisements or solicitations for employment by any party.

6. CONFIDENTIALITY

- a) For the purposes of this Agreement, "**Confidential Information**" means any non-public information and data disclosed by one party (the "disclosing party") to the other (the "receiving party"), including but not limited to proprietary, developmental, technical, product, marketing, sales, operating, business, employee, performance, cost and pricing information, as well as the disclosing party's know-how, methods, strategies, processes, data, inventions, product concepts, computer programming techniques, and all record bearing media containing or disclosing such information and techniques which is disclosed pursuant to this Agreement; provided that such information, if disclosed in written form, is clearly marked as "confidential" or with a similar legend. Confidential Information specifically includes any samples, models or prototypes or parts thereof, the Proposal, as well as the terms and conditions (but not the fact of the existence) of this Agreement, and any Third Party Information. "**Third Party Information**" means any Confidential Information owned by a third party which the disclosing party is under an obligation to protect, and which is disclosed to the receiving party in connection with the performance of this Agreement.

b) Confidential Information exchanged between the parties pursuant to this Agreement:

- i) shall not be copied or distributed, disclosed or disseminated in any way or form by the receiving party to anyone other than to its own employees and contractors solely for the purpose of fulfilling such party's obligations under this Agreement, and who are advised as to the confidential and proprietary nature of such Confidential Information and the restrictions on use as specified in this Agreement;
- ii) shall be treated by the receiving party with the same degree of care to avoid disclosures to any third party as it uses to protect its own confidential information of like importance, but no less than a reasonable degree of care;
- iii) shall not be used by the receiving party for its own purposes or for any other purpose except for the purpose of exercising its rights and performing its obligations under this Agreement, and in business arrangements with the disclosing party, without the disclosing party's prior written consent; and
- iv) shall remain the property of and be returned to the disclosing party (along with all copies thereof) within thirty (30) days of the termination of this Agreement, or earlier receipt by the receiving party of a written request by the disclosing party requesting the Confidential Information to be returned; provided, however that each party may retain for its records one secure copy of the other's Confidential information.

c) None of the obligations set out in Section (b) shall apply to any information which the receiving party can show:

- i) has become generally known in the trade or the public through no act of the receiving party;
- ii) has been disclosed in good faith to the receiving party by a third party having legitimate possession and the right to make such disclosures;
- iii) was in the legitimate possession of the receiving party, without obligation of confidentiality, prior to disclosure by the disclosing party; or
- iv) was developed independently by the receiving party without reference to the disclosing party's Confidential Information.

d) Each party represents and warrants that it has the right to disclose all Confidential Information disclosed by it under this Agreement. Either party shall have the right to refuse to accept any information under this Agreement, and nothing herein shall obligate either party to disclose to the other party any particular information; provided, however, that StarFish shall not be liable for any inability or delay in performing the Services which results from the failure of ENDRA to provide any information reasonably requested by StarFish.

e) Each party recognizes and acknowledges the confidential and proprietary nature of any Confidential Information disclosed by the other party and acknowledges the irreparable damage that could result to the disclosing party if it is disclosed to a third party or used for any unauthorized purposes without the disclosing party's prior written consent. Accordingly, without prejudice to any other rights and remedies otherwise available, each receiving party agrees to the granting of injunctive and/or other equitable relief to a disclosing party in respect of any actual or threatened breach of this Agreement, without the necessity of proving actual damages or posting bond or other security.

- f) Subject only to Section 6(c), a receiving party's obligations with respect to Confidential Information shall survive for a period of seven (7) years from the date of disclosure of the information notwithstanding the earlier termination or expiry of this Agreement.
- g) Subject to Section 6(i), and provided the payment conditions of Section 4(b) are satisfied, this Section 6 shall not limit the use or publicity by ENDRA of any Deliverables it purchases under this Agreement following delivery thereof by StarFish.
- i) Neither party may issue press releases or make additional information regarding the business relationship between the parties publicly available unless it shall have first obtained the consent of the other party.

7. TERM AND TERMINATION

- a) This Agreement shall become effective as of the date that it is executed by the last of the parties to sign, and shall continue in effect until the full and final completion of both party's obligations under this Agreement, including all statements of work attached hereto or which may be attached hereafter (the "**Term**").
- b) Either party may terminate this Agreement upon not less than sixty (60) days prior written notice to the other party, with or without cause.
- c) Upon the termination or expiry of this Agreement for any reason, ENDRA shall promptly (but in any event, within 30 days) pay to StarFish all unpaid amounts due for any part of the Services and Deliverables completed as of the effective date of termination or expiry. Upon receipt of payment, StarFish shall promptly deliver to ENDRA all full or partial Deliverables existing as of the date of termination, and any other materials which it is obliged to deliver in accordance with Section 4(a). In the event of early termination, StarFish shall assist at ENDRA's request with the transfer of the preparation of the Deliverables and performance of the Services to another party in order to minimize any delay caused by such termination, and ENDRA will compensate StarFish for its reasonable costs associated therewith.
- d) Sections 4, 5, 6, 7(c), 7(d), 8 and 10 shall survive the expiry or termination of this Agreement for any reason, in accordance with their terms.

8. LIMITATION OF LIABILITY AND INDEMNITY

- a) StarFish's, its officers', shareholders', directors', employees' and contractors' total liability to ENDRA and to any other party for all losses, costs and damages from any and all causes whatsoever, regardless of the form of action, whether in contract, tort or otherwise, including negligence and gross negligence, shall in the aggregate be limited to the total amount paid to StarFish under this Agreement; provided, however, that the limitations set forth in this Section 8(a) shall not apply to StarFish's breach of any representations or warranties under Section 4(g) or StarFish's failure to comply with its obligations of confidentiality under Section 6, for which the limits shall be \$2 million.

- b) Notwithstanding any other provision of this Agreement or theory of law, ENDRA shall defend, indemnify and hold StarFish, its officers, shareholders, directors, employees and contractors harmless from and against any and all liabilities, losses, costs, court costs, damages, expenses, and reasonable legal, accounting and other professional fees, resulting from or arising out of: (i) any breach by ENDRA of this Agreement; (ii) any violation by ENDRA of applicable law; or (iii) any grossly negligent acts, grossly negligent omissions or willful misconduct by ENDRA.

9. FORCE MAJEURE

- a) Except for monetary payment obligations, neither party shall be liable to the other by reason of any failure to perform in accordance with the terms of this Agreement if such failure arises out of causes wholly or substantially beyond the reasonable control of the defaulting party. Such causes may include, but shall not be limited to, unavailability of communications facilities, acts of God or the public enemy, acts of the other party, acts of civil or military authority, fires, strikes, power surges or the unavailability of energy sources delay in transportation, riots or war.

10. GENERAL

- a) Each party represents and warrants that it has full power and authority to enter into, execute, deliver, and perform its obligations under this Agreement and the person signing this Agreement on behalf of each party has been properly authorized and empowered to enter into this Agreement.
- b) This Agreement, including its schedules, constitutes the entire Agreement between the parties. Except as specifically provided in this Agreement, no change, amendment or waiver hereof shall be valid unless it is in writing and is executed by both parties.
- c) Each provision of this Agreement is intended to be severable. If any one or more provisions, or part thereof, in the Agreement should be ruled wholly or partly invalid or unenforceable by a court having competent jurisdiction, then the remaining provisions of the Agreement shall be unaffected and shall continue in full force and effect.
- d) Waiver of a breach of this Agreement or any power arising upon default under this Agreement must be in writing and signed by the party granting the waiver. A waiver shall not be or be construed to be a general waiver and will relate only to the particular breach in respect of which it is made. A breach of this Agreement is not waived by a failure to exercise, a delay in exercising, or the partial exercise of any power.

- e) This Agreement is binding on and shall enure to the benefit of the parties, their successors and assigns.
- f) The Laws of the State of Delaware shall govern this Agreement and the parties hereto irrevocably attorn to the exclusive jurisdiction of the Courts of the State of Michigan and the courts of appeal therefrom.
- g) By executing this Agreement, the parties acknowledge and agree that they have reviewed these terms and conditions, have had the opportunity to consult with legal counsel, and agree to be legally bound hereby.
- h) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

/s/ John Walmsley
Signed

John Walmsley, COO
Name, Title

StarFish Product Engineering Inc.
Company

Witness

1 November 2017
Date (MMM DD, YYYY)

/s/ Francois Michelin
Signed

Francois Michelin, CEO
Name, Title

ENDRA Life Sciences, Canada, Inc.
Company

/s/ Scott Belanger
Witness

10 31 2017
Date (MMM DD, YYYY)

Subsidiaries of the Registrant

ENDRA Life Sciences Canada Inc. is a corporation formed under the laws of Ontario, Canada in July 2017.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of ENDRA Life Sciences Inc.

We consent to the incorporation by reference in the registration statement (File Number: [333-218894](#)) on Form S-8 of ENDRA Life Sciences Inc. of our report dated March 19, 2018, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, relating to the balance sheets of ENDRA Life Sciences Inc. as of December 31, 2017 and 2016, and the related statements of operations, stockholders' equity (deficit) and cash flows for the years then ended, appearing in this Annual Report on Form 10-K of ENDRA Life Sciences Inc.

/s/ RBSM LLP

Henderson, NV

March 20, 2018

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Francois Michelin, certify that:

1. I have reviewed this Annual Report on Form 10-K of ENDRA Life Sciences Inc. ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 20, 2018

/s/ Francois Michelin

Name: Francois Michelin

Title: Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David R. Wells, certify that:

1. I have reviewed this Annual Report on Form 10-K of ENDRA Life Sciences Inc. ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 20, 2018

/s/ David R. Wells

Name: David R. Wells

Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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

In connection with the Annual Report on Form 10-K of ENDRA Life Sciences Inc. (the "Company") for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Francois Michelin, Chief Executive Officer of the Company, and David R. Wells, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to ENDRA Life Sciences Inc. and will be retained by ENDRA Life Sciences Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Francois Michelin

Name: Francois Michelin
Title: Chief Executive Officer
(Principal Executive Officer)
Date: March 20, 2018

/s/ David R. Wells

Name: David R. Wells
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
Date: March 20, 2018
