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

**FORM 10-K**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____**

**Commission File Number: 001-37714**

# Sensus Healthcare, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **27-1647271** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **851 Broken Sound Pkwy., NW #215, Boca Raton, Florida** | **33487** |
| (Address of principal executive office) | (Zip Code) |

**(561) 922-5808**
(Registrant's telephone number, including area code)

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

| | |
|---|---|
| Common Stock, par value $0.01 per share | Nasdaq Stock Market, LLC |
| Warrants to Purchase Common Stock (expiring June 8, 2019) | 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

| Large accelerated filer ☐ | Accelerated filer ☐ | Non-accelerated filer ☐ (Do not check if smaller reporting company) | Smaller reporting 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 Exchange Act). Yes ☐ No ☒
The aggregate market value of the common equity held by non-affiliates of the registrant on June 30, 2018, the last business day of the registrant's most recently completed second quarter, was $58,772,343 based on the closing price of $7.26 per share of common stock on the Nasdaq Capital Market on that date. For this purpose, all outstanding shares of common stock have been considered held by non-affiliates, other than the shares beneficially owned by directors, officers and certain 5% stockholders of the registrant; certain of such persons disclaim that they are affiliates of the registrant.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

| Class | Outstanding at March 8, 2019 |
|---|---|
| Common Stock, $0.01 par value per share | 16,404,820 |

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of our Proxy Statement for the Annual Meeting of Stockholders to be held on June 7, 2019, are incorporated by reference in Part III.

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**SENSUS HEALTHCARE, INC.**
**ANNUAL REPORT ON FORM 10-K**
**TABLE OF CONTENTS**

**INTRODUCTORY NOTE**
**Caution Concerning Forward-Looking Statements**

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, among others, statements about our beliefs, plans, objectives, goals, expectations, estimates and intentions that are subject to significant risks and uncertainties and are subject to change based on various factors, many of which are beyond our control. The words "may," "could," "should," "would," "will," "believe," "anticipate," "estimate," "expect," "intend," "plan," "target," "goal," and similar expressions are intended to identify forward-looking statements.

All forward-looking statements, by their nature, are subject to risks and uncertainties. Our actual future results may differ materially from those set forth in our forward-looking statements.

In addition to those risks discussed in this Annual Report under *Item 1A Risk Factors*, factors that could cause our actual results to differ materially from those in the forward-looking statements, include, without limitation:

- our ability to achieve and sustain profitability;
- market acceptance of our products;
- our ability to successfully commercialize our products;
- our ability to compete effectively in selling our products and services, including responding to technological change and cost containment efforts of our customers;
- the regulatory requirements applicable to us and our competitors, including any adverse regulatory action taken against us;
- our need and ability to obtain additional financing in the future, as well as complying with the restrictions our existing revolving credit facility imposes;
- our ability to expand, manage and maintain our direct sales and marketing organizations;
- our actual financial results may vary significantly from forecasts and from period to period;
- our ability to successfully develop new products, improve or enhance existing products or acquire
- complementary products, technologies, services or businesses;
- our ability to obtain and maintain intellectual property of sufficient scope to adequately protect our products, including the SRT-100, and our ability to avoid infringing or otherwise violating the intellectual property rights of third parties;
- market risks regarding consolidation in the healthcare industry;
- the willingness of healthcare providers to purchase our products if coverage, reimbursement and pricing from third party payors for procedures using our products declines;
- the level and availability of government and third-party payor reimbursement for clinical procedures using our products;
- our ability to effectively manage our anticipated growth, including hiring and retaining qualified personnel;
- our ability to manufacture our products to meet demand;
- our reliance on third party manufacturers and sole- or single-source suppliers;
- our ability to reduce the per unit manufacturing cost of our products;
- our ability to efficiently manage our manufacturing processes;
  the regulatory and legal risks, and certain operating risks, that our international operations subject us to;
  off label use of our products;
- information technology risks including the risk from cyberattack;
- the fact that product quality issues or product defects may harm our business;
  the accuracy of our financial statements and accounting estimates, including allowances for accounts receivable and inventory obsolescence;
- any product liability claims;
- limited trading in our shares and the concentration of ownership of our shares;
- cyberattacks and other data breaches and the adverse effect on our reputation;
- new legislation, administrative rules, or executive orders, including those that impact taxes and international trade regulation;
- the provisions in our certificate of incorporation, bylaws, or Delaware law that discourage takeovers or that limit certain disputes to be brought exclusively in the Delaware Court of Chancery; the concentration of sales in our customers in the U.S. and China; and



- our ability to manage the risk of the foregoing.

However, other factors besides those listed in *Item 1A Risk Factors* or discussed in this Form 10-K also could adversely affect our results, and you should not consider any such list of factors to be a complete set of all potential risks or uncertainties. Any forward-looking statements made by us or on our behalf speak only

as of the date they are made. We do not undertake to update any forward-looking statement, except as required by applicable law.

**PART I.**

**Item 1. BUSINESS**

**Overview**

We are a medical device company that is committed to providing highly effective, non-invasive and cost-effective treatments for both oncological and non-oncological skin conditions. We use a proprietary low-energy X-ray technology known as superficial radiation therapy (SRT), which is a result of over a decade of dedicated research and development. We have successfully incorporated SRT into our portfolio of treatment devices: the SRT-100™, SRT-100+™ and SRT-100 Vision™. To date, SRT technology has been used to effectively and safely treat oncological and non-oncological skin conditions in thousands of patients around the world. With the introduction of Sculptura™, we are branching out into cancer treatment that goes far beyond skin and will provide a revolutionary treatment option for patients around the world.

We completed an initial public offering in June 2016 and in February 2018, we opened a wholly owned subsidiary in Israel.

**Our Products and Services**

***SRT-100***

The SRT-100 is a photon x-ray low energy superficial radiotherapy system that provides patients an alternative to surgery for treating non-melanoma skin cancers, including basal cell and squamous cell skin cancers and other skin conditions such as keloids. The SRT-100 is especially effective in treating primary lesions that would otherwise be difficult or require extensive surgery involving sensitive areas of the head and neck regions, such as the fold in the nose, eyelids, lips, corner of the mouth, and the lining of the ear, that would otherwise lead to a less than desirable cosmetic outcome. Superficial radiation therapy treatment procedures do not require the use of anesthetics and eliminates the need for skin grafting. We believe that the SRT-100 provides healthcare providers and patients with a safe, virtually painless, and substantially non-scarring treatment option for non-melanoma skin cancer and other skin conditions, such as keloids. It allows dermatologists to retain non-melanoma skin cancer patients, rather than referring them to specialists, while offering radiation oncologists an alternative to costly linear accelerator–based treatments with a process that is less invasive, more time-efficient, and improves practice economics. Our revenue is primarily derived from sales of our SRT-100 product line. The SRT-100 provides the following clinical and functional advantages:

- Easy touch automatic set-up procedure, including automatic x-ray tube warm-up procedures;
- Specially designed control console for medical physicists and service technicians which provides integrated safety and back-up timer controls, automatic system conditioning procedures, calibration, x-ray output verification and system parameters including last treatment status information;
- Advanced patient record management with integrated enterprise workflow management;
- Compact mobile design with a small 30” x 30” footprint and unique scissor x-ray tube arm movements providing a large range of motion for patient access and treatment; and
- High reliability and MTBF (mean time between failures) performance that assure availability for the patients and practitioners and lower the total cost of ownership.



***SRT-100 Vision***

The SRT-100 Vision provides customers with additional options compared to the SRT-100 base model. These additional options allow for dedicated treatment planning and full treatment progression documentation in a patient’s record. The SRT-100 Vision provides the user with a unique superficial radiation therapy-tailored treatment planning application that integrates the embedded high frequency ultrasound imaging module, volumetric tumor analysis, beam margins planning, and comprehensive dosimetry parameters. This allows the user to precisely and more accurately plan and prescribe the patient-specific treatment course to maximize patient outcomes and workflow efficiency. The SRT-100 Vision also offers a comprehensive control console and workflow management that provides full record and treatment tracing, operator-level access and functional control, audio-visual patient and treated lesion monitoring, and advanced dosimetry setting and tracing.

***SRT-100 Plus***

In August 2018, we announced the FDA clearance of our SRT-100+. The SRT-100+ offers all the same features as the SRT-100, with the addition of:

- An expanded energy range for customized, more precise treatment
- Remote diagnostics, including operation tracking
- New X-ray tube with extended functionality and performance
- Advanced console and enhanced system mobility to optimize clinical practice

***Sculptura***

In February 2019, we announced the FDA clearance of our Sculptura product, which is our proprietary robotic Intraoperative Radiation Therapy (IORT) system that uses patented Beam Sculpting™ capabilities to treat various cancers during surgery. This system has the potential to give surgeons and radiation oncologists at hospitals and cancer centers the ability to eliminate weeks of post-operative radiation treatments that patients typically must undergo after surgery and also result in similar or better outcomes to current radiation treatments today, with significantly less collateral damage. Sculptura has several exclusive features, including 3D Beam Sculpting™, respiratory motion tracking, embedded image guidance and treatment area illumination.

***Sentinel service program***

We offer the Sentinel service program, which provides our customers comprehensive protection for their systems. The Sentinel service program covers all parts and labor for the period of the contract and one annual preventive maintenance session that includes cooling system maintenance, high voltage loop maintenance, filters and system cleaning, and system touch-ups, should they be required during the preventative maintenance session.

We also provide turnkey pre-and post-sale services that include the following:

- Providing a pre-install kit for the contractors to prepare the treatment room;
- Room retrofit and shielding;
- System shipping coordination and installation;
- System commissioning by a medical physicist (through a national physics network);
- System registration with the state and daily workflow documentation preparation;
- Clinical applications training with the customer’s superficial radiation therapy staff; and
- Treating the first scheduled patients with our customers (onsite applications training).

***Consumables***

We sell disposable lead shielding replacements, disposable radiation safety items, such as aprons, and eye shields, and disposable applicator tips, which are used to

treat various sized lesions and different areas of the body.



**Competition**

The medical device industry is highly competitive, subject to rapid technological change and is significantly affected by new product introductions and market activities of other participants. Our currently marketed products, and any future products we commercialize, will compete against healthcare providers who use traditional surgical treatment options, such as Mohs surgery, as well as medical device companies that offer other treatment options for the conditions our products are designed to treat. As of December 31, 2018, we had three primary medical device company competitors:

- Xstrahl Medical (headquartered in the United Kingdom and with U.S. headquarters in Georgia)
- Xoft (a subsidiary of iCAD, headquartered in New Hampshire)
- Elekta (headquartered in Sweden and with U.S. headquarters in Georgia)

Xstrahl Medical primarily focuses on clinical and research x-ray therapy devices and solutions. We believe most of Xstrahl Medical's installed base is comprised of higher energy devices located in Europe.

Both Xoft and Elekta offer products that are considered Electronic Brachytherapy ("eBx") devices. Both eBx products have more limited capabilities than our products as to the size of lesions that can be treated as well as the energy levels that can be used, and require expensive consumables.

Many of our current and potential competitors have significantly greater financial, technical, marketing and other resources than we do and may be able to devote greater resources to the development, promotion, sale and support of their products. Our competitors may also have more extensive customer bases and broader customer relationships than we do, including relationships with our potential customers. In addition, many of these companies and healthcare providers have longer operating histories and greater brand recognition than we do. Because of the size of the markets and the high growth profile of the products in which we compete, other companies may dedicate significant resources to developing competing products. Additionally, we may also face competition from smaller companies that have developed or are developing similar technologies for our addressable markets. We believe that the principal competitive factors in our markets include:

- improved outcomes for medical conditions;
- acceptance by doctors treating non-melanoma skin cancer and keloids;
- potential greater acceptance by the patient community;
- potential greater ease of use and reliability;
- product price and qualification for reimbursement;
- technical leadership and superiority;
- effective marketing and distribution; and
- speed to market.

We may be unable to compete effectively against our competitors in regard to any one or all of these factors. Our ability to compete effectively will depend on the acceptance of our products by dermatologists, radiation oncologists, hospitals and patients, and our ability to achieve better clinical outcomes than products developed by our existing or future competitors. In addition, certain of our competitors could use their superior financial resources to develop products that have features or clinical outcomes similar or superior to our products, which would harm our ability to successfully compete.

**Sales and Marketing**

We focus mainly on two primary markets, private dermatology practices and radiation oncologists in both private and hospital settings. We currently employ a multi-tier sales strategy to optimize geographic coverage and focus on what we perceive to be our key markets. This multi-tier sales model uses a direct sales force in the U.S., as well as international dealers and distributors. We plan to continue selling and marketing our products to both the dermatology and radiation oncology markets concurrently.



***Dermatology Market***

Private dermatology practices in the U.S. represent the point of entry for most non-melanoma skin cancer patients. We believe the SRT-100 offers dermatologists a competitive advantage by allowing them to retain patients for the treatment of non-melanoma skin cancer, rather than referring them out to specialists for Mohs surgery or other radiation procedures. In addition to non-melanoma skin cancers, our FDA-approved indications include, among others, keloids, Kaposi's Sarcoma, Actinic Keratosis, Metatypic Carcinoma, Cutaneous Appendage Carcinoma and other malignant skin tumors. Our SRT-100 is currently being used by over 100 U.S. dermatology practices in the treatment of keloids. Since our clearance in China in July 2017, it is also being used to treat Keloids in China. We are continuing to drive our research and development to expand our indications into new areas of treatment, including psoriasis.

***Radiation Oncology Market***

For licensed radiation oncologists in the U.S., we believe the SRT-100 offers a simpler, faster method of treatment with a better overall patient experience. Our SRT-100 system offers oncologists the ability to free up more expensive radiation equipment, such as linear accelerators, for more complex procedures while providing patients with effective, non-invasive treatment options for non-melanoma skin cancer. Our Sculptura system has the potential to give surgeons and radiation oncologists at hospitals and cancer centers the ability to eliminate weeks of post-operative radiation treatments that patients have to undergo after surgery and also result in similar or better outcomes to current radiation treatments today, with much less collateral damage. Sculptura has several exclusive features, including 3D Beam Sculpting™ and respiratory motion tracking to the embedded image guidance and treatment area illumination.

***Other Markets***

We also believe that both plastic and general surgery markets present growth opportunities for our product offerings. With FDA clearance to treat keloids through superficial radiation therapy, plastic surgeons are recognizing the opportunity to be able to provide an effective treatment solution for this benign tumor. Additionally, we believe that plastic surgeons view the non-melanoma skin cancer market as a growth opportunity that can supplement their existing services. We believe there is an opportunity to also provide superficial radiation therapy in a prophylactic manner for various surgical procedures to reduce the formation of keloids. Within the new healthcare reform environment, superficial radiation therapy can provide hospitals and surgery centers with a direct measurable impact on clinical outcomes for certain procedures, including joint replacement procedures, bypass surgery, and OBGYN/C-section procedures, among others.

***Global Focus***

As of December 31, 2018, we had an installed base of 395 units in 17 countries. Our customer list includes leading cancer centers, dermatology practices, hospitals and plastic surgery clinics, which we believe further validates our targeted marketing approach led by our direct sales teams and our global distribution partners.

**Manufacturing and Supply**

We currently use a third party located in the U.S. to manufacture our products. In July 2010, we entered into a manufacturing agreement with RbM Services, LLC ("RbM") pursuant to which RbM agreed to manufacture our SRT-100 products. We pay a fixed price per unit under the terms of this agreement, subject to annual adjustments due to changes in the cost of materials. The initial term of this agreement was three years with successive one-year renewals thereafter. We continue to do business with RbM, although we or RbM may terminate the agreement upon 90 days' written notice or upon at least 60 days' notice prior to the end of each additional one-year renewal period. We believe our third party manufacturer meets FDA, International Organization for Standardization, or ISO, and other quality standards. We maintain internal policies, procedures and supplier management processes to ensure that our third party manufacturer is meeting applicable quality standards. To date, we have not experienced any difficulty in locating and obtaining the materials necessary to meet the demand for our products, and we believe manufacturing capacity is sufficient to meet global market demand for our products for the foreseeable future.



We believe this third party manufacturing relationship initially allowed us to work with a supplier that has well-developed specific competencies while minimizing our capital investment, controlling costs and shortening cycle times, all of which we believe allowed us to compete with our competitors. However, we are in the process of adding other third party manufacturers and exploring the possibility of bringing certain manufacturing functions in-house, which could include the acquisition of equipment and other fixed assets or the acquisition or lease of a manufacturing facility.

We have a single preferred supplier for the x-ray tubes and other major components used in our products. We believe our preferred suppliers have superior products; however, we also believe that the products of alternate suppliers would be adequate for our products. Although we generally do not have a contractual relationship with our preferred suppliers we do not anticipate any material disruptions to our supply of major components. We believe that adequate supplies of major components are readily accessible from alternate suppliers.

**Intellectual Property**

We actively seek to protect the intellectual property that we believe is important to our business, including seeking and maintaining patents that cover our products. We also rely on trademarks to build and maintain the integrity of our brand.

We own two issued U.S. patents. Our patents pertain to technology in the specialized field of superficial radiotherapy treatment. The following patents were issued between August 2007 and September 2008 and were assigned to us when we acquired the technology from Topex:

- U.S. Patent No. 7,372,940: Radiation therapy system with risk mitigation
- U.S. Patent No. 7,263,170: Radiation therapy system featuring rotatable filter assembly

The following patents were issued to us in 2018:

- Russia Patent No. 26333322: Hybrid Ultrasound-Guided Superficial Radiotherapy System and Method
- China Patent No. ZL201380013491.7: Hybrid Ultrasound-Guided Superficial Radiotherapy System and Method

A total of 22 patent applications are pending and additional patent applications are in process.

We also own three U.S. trademark registrations and currently have eight trademark applications that are pending.

We also rely on trade secrets and other unpatented proprietary rights to develop and maintain our competitive position. We seek to protect our unpatented proprietary rights through a variety of methods, including confidentiality agreements with employees, consultants and others who may have access to our proprietary information. We also require our employees to execute invention assignment agreements with respect to inventions arising from their employment.

No patents or trademarks may ever be issued or registered as a result of our pending or future applications for such intellectual property. Even if any such patents or trademarks are ultimately issued or registered, they, or any of our other intellectual property, may not provide us with any meaningful protection or competitive advantage. Our intellectual property could be challenged, invalidated, circumvented, infringed or misappropriated. In addition, third parties have claimed, and in the future may claim, that we, our customers, licensees or other parties indemnified by us are infringing upon their intellectual property rights.

**Government Regulation**

Our business is subject to extensive federal, state, local and foreign laws and regulations including those relating to the protection of the environment, health and safety. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change or new laws may be enacted. Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations and relationships with our customers and suppliers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business. For the years ended December 31, 2018 and 2017, we incurred approximately $1,039,000 and $866,000, respectively, in expenses related to regulatory compliance and quality standards.



***U.S. Food and Drug Administration (FDA) Regulation of Medical Devices***

The Federal Food, Drug and Cosmetic Act, or FDCA, and FDA regulations establish a comprehensive system for the regulation of medical devices intended for human use. Our products include medical devices that are subject to these, as well as other federal, state, and local laws and regulations. FDA is responsible for the overall enforcement of quality, regulatory and statutory requirements governing medical devices. Our regulated medical devices include our SRT-100 product line.

FDA classifies medical devices into one of three classes — Class I, Class II, or Class III — depending on their level of risk and the types of controls that are necessary to assure device safety and effectiveness. The class assignment determines the type of premarketing submission or application, if any, that will be required before marketing in the U.S. Our devices are Class II devices under the FDA's classification system.

- Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to "general controls" — e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all classes of medical devices.

- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and "special controls" — e.g., special labeling, compliance with industry standards, and postmarket surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification (510(k)) process, in accordance with 21 CFR, Part 807 requirements.

- Class III devices present the highest risk. These devices generally are life-sustaining, life-supporting, or for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide a reasonable assurance of safety and

effectiveness. Class III devices are subject to general controls and typically require approval of a premarket approval application, or PMA, in accordance with 21 CFR, Part 814, before marketing.

Unless it is exempt from premarket review requirements, a medical device must receive marketing authorization from the FDA prior to being commercially distributed in the U.S. The most common pathways for obtaining marketing authorization are 510(k) clearance and PMA. With the enactment of the Food and Drug Administration Safety and Innovation Act, or the FDASIA, the availability of a *de novo* pathway was facilitated for certain low- to moderate-risk devices that do not qualify for the 510(k) pathway due to the absence of a predicate device.

*510(k) pathway*

As of December 31, 2018, all of our products were subject to the 510(k) requirement or are exempt from the 510(k) requirement. The 510(k) review process compares a new device to an existing legally marketed device. Through the 510(k) process, the FDA determines whether the new medical device is "substantially equivalent" to the existing legally marketed device (i.e., predicate device) that is not subject to PMA requirements. "Substantial equivalence" means that the proposed new device: (a) has the same intended use as the predicate device; (b) has the same or similar technological characteristics as the predicate device; (c) has supporting information submitted in the 510(k) demonstrates that the proposed device is as safe and effective as the predicate device; and (d) does not raise different questions of safety and effectiveness than the predicate device.

To obtain 510(k) clearance, we must submit a 510(k) application containing sufficient information and data to demonstrate that our proposed device is substantially equivalent to a legally marketed predicate device. This data generally includes non-clinical performance testing (e.g., software validation, bench testing electrical safety testing), but may also include clinical data. Typically, it takes approximately four months for the FDA to complete its review of a 510(k) submission; however, it can take significantly longer and clearance is never assured. During its review of a 510(k), the FDA may request additional information, including clinical data, which may significantly prolong the review process. After completing its review of a 510(k), the FDA may issue an order, in the form of a letter, that finds the device to be either (1) substantially equivalent to the predicate device and states that the device can be marketed in the U.S., or (2) not substantially equivalent to the predicate device and states that device cannot be marketed in the U.S. Depending upon the reasons that the FDA finds the new device to not be substantially equivalent to the predicate device, the device may need to be approved through the PMA pathway (discussed below) prior to commercialization. A new medical device for which there is no substantially equivalent device is automatically designated a Class III device. Depending on the nature of the new device, the manufacturer may request the FDA to make a risk-based determination of the new device and to reclassify it as a Class I or Class II device. This process is referred to as the *de novo* process. If the FDA agrees, the new device will be reassigned to the appropriate other class. If the FDA does not agree, the manufacturer must submit a PMA prior to commercialization. We have received FDA 510(k) clearances for our SRT-100 and SRT-100 Vision.



After a device receives 510(k) clearance, any modification that could significantly affect the safety or effectiveness of the device, or that would constitute a major change in its intended use, including significant modifications to any of our products, requires a new 510(k) clearance. The FDA relies on each manufacturer to make and document this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. We have made and plan to continue to make minor product enhancements that we believe do not require new 510(k) clearances. However, we expect to confer with the FDA on planned changes that may require a special, abbreviated or traditional 510(k) submission. If the FDA disagrees with our determination regarding whether a new 510(k) clearance was required for these modifications, we may need to cease marketing or recall the modified device. The FDA may also subject us to other enforcement actions, including, but not limited to, issuing a warning letter or untitled letter to us, seizing our products, imposing civil penalties, or initiating criminal prosecution.

*Premarket approval pathway*

As of December 31, 2018, we did not market any devices that were subject to PMA requirements. Unlike the 510(k) pathway, the PMA approval process requires an independent demonstration of the safety and effectiveness of a device before the device can be commercialized. PMA is the most stringent type of device marketing application required by FDA. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. A PMA application generally includes extensive information about the device including the results of clinical testing conducted with the device and a detailed description of the manufacturing process.

After a PMA application is accepted for review, the FDA begins an in-depth review of the submitted information. FDA regulations provide 180 days to review the PMA and make a determination; however, the review time is typically longer (e.g., 1 – 3 years). During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside of the FDA may be convened to review and evaluate the data supporting the application and provide recommendations to the FDA as to whether the data provide a reasonable assurance that the device is safe and effective for its intended use. In addition, the FDA generally will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation, or QSR, which imposes comprehensive development, testing, control, documentation and other quality assurance requirements for the design and manufacturing of a medical device.

Based on its review, the FDA may (1) issue an order approving the PMA, (2) issue a letter stating the PMA is "approvable" (e.g., minor additional information is needed), (3) issue a letter stating the PMA is "not approvable," or (4) issue an order denying PMA. A device subject to PMA review cannot be marketed until the FDA issues an order approving the PMA. As part of a PMA approval, the FDA may impose post-approval conditions intended to ensure the continued safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution, and requiring the collection of additional clinical data. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including withdrawal of the approval.

Most modifications to a PMA approved device, including changes to the design, labeling, or manufacturing process, require prior approval before being implemented. Prior approval is obtained through submission of a PMA supplement. The type of information required to support a PMA supplement and the FDA's time for review of a PMA supplement vary depending on the nature of the modification.



*Clinical trials*

Clinical trials of medical devices in the U.S. are governed by the FDA's Investigational Device Exemption regulation, in accordance with 21 CFR, Part 812. This regulation places significant responsibility on the sponsor of the clinical study including, but not limited to, choosing qualified investigators, monitoring the trial, submitting required reports, maintaining required records, and assuring investigators obtain informed consent, comply with the study protocol, control the disposition of the investigational device, submit required reports, etc.

Clinical trials of significant risk devices (e.g., implants, devices used in supporting or sustaining human life, devices of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health) require FDA and Institutional Review Board approval prior to starting the trial. FDA approval is obtained through submission of an Investigational Device Exemption application. Clinical trials of non-significant risk devices (i.e. devices that do not meet the regulatory definition of a significant risk device) only require Institutional Review Board approval before starting. The clinical trial sponsor is responsible for making the initial determination of whether a clinical study is significant risk or non-significant risk; however, a reviewing Institutional Review Board or the FDA may review this decision and disagree with the determination.

An Investigational Device Exemption application must be supported by appropriate data, such as performance data, animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the clinical study protocol is scientifically sound. There is no assurance that submission of an Investigational Device Exemption will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if,

among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk.

As noted above, the FDA may require a company to collect clinical data on a device in the post-market setting. The collection of such data may be required as a condition of PMA approval. FDA also has the authority to order, via a letter, a post-market surveillance study, in accordance with 21 CFR, Part 822, for certain devices at any time after they have been cleared or approved. We do not expect to launch clinical trials subject to the Investigational Device Exemption regulations for future products. Also, our products are not currently subject to any required post-market surveillance studies.

*Pervasive and continuing FDA regulation*

After a device is entered into commerce in the U.S., regardless of its classification or premarket pathway, numerous additional FDA requirements generally apply. These include:

- Establishment registration and device listing requirements, in accordance with 21 CFR, Part 807;
- Quality System Regulation requirements, which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices, in accordance with 21 CFR, Part 820;
- Labeling requirements, which mandate the inclusion of certain content in device labels and labeling, and which also prohibit the promotion of products for uncleared or unapproved, i.e., "off-label," uses;
- Medical Device Reporting regulation, which requires that manufacturers and importers report to FDA if their device 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 it were to recur, in accordance with 21 CFR, Part 803; and
- Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to FDA recalls (i.e., corrections or removals) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; manufacturers and importers must keep records of recalls that they determine to be not reportable, in accordance with 21 CFR, Part 806.



The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include, but is not limited to, the following sanctions:

- Issuance of Form 483 observations during a facilities inspection;
- Untitled letters or warning letters;
- Fines, injunctions and civil penalties;
- Consent Decree, which forces improvements in the quality management system through the use of the federal courts;
- Recall or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Refusing our request for 510(k) clearance or premarket approval of new products;
- Withdrawing 510(k) clearance or premarket approvals that are already granted; and
- Criminal prosecution.

We are subject to unannounced establishment inspections by the FDA, as well as other regulatory agencies overseeing the implementation of and compliance with applicable state public health regulations. These inspections may include our suppliers' facilities.

***International***

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area, or EU/EEA, requires a CE conformity mark in order to market medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE or FDA clearance or approval, although others, such as China, Brazil, Canada and Japan require separate regulatory filings.

In the EEA, our devices are required to comply with the essential requirements of the EU Medical Devices Directive (93/42/EEC). Compliance with these requirements entitles us to affix the CE marking of conformity to our medical devices, without which they cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE marking of conformity we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up an EC Declaration of Conformity which allows us to affix the CE mark to our products.

Further, the advertising and promotion of our products in the EEA is subject to the laws of individual EEA Member States implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State laws governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

We have obtained approval to sell our products in Europe, China, Canada, Israel, Russia and Mexico, and we are currently seeking approval in several other countries.



***Sales and Marketing Commercial Compliance***

Federal anti-kickback laws and regulations prohibit, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for, or to induce either the referral of an individual, or the purchase, order or recommendation of, any good or service paid for under federal healthcare programs such as the Medicare and Medicaid programs. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions.

In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Off-label promotion has been pursued as a violation of the federal false claims laws. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. Additionally, the majority of states in which we market our products have similar anti-kickback, false claims, anti-fee splitting and self-referral laws, which may apply to items or services reimbursed by any third party payor, including commercial insurers, and violations may result in substantial civil and criminal penalties.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers which has led to an unprecedented level of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, the company may be required to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement.

The U.S. and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased U.S. government oversight and enforcement of the Foreign Corrupt Practices Act. Whenever a governmental authority concludes that we are not in compliance with applicable laws or regulations, that authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees and can recommend criminal prosecution. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of devices we distribute.

Additionally, the commercial compliance environment is continually evolving in the healthcare industry as some states, including California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The Affordable Care Act also imposes reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. Device manufacturers are also required to report and disclose any investment interests held by physicians and their family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

***Healthcare Fraud and Abuse***

Healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally funded healthcare programs. The federal Anti-Kickback Statute prohibits unlawful inducements for the referral of business reimbursable under federally funded healthcare programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The Anti-Kickback Statute is subject to evolving interpretations. For example, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consultant arrangements with physicians. The majority of states also have anti-kickback laws which establish similar prohibitions that may apply to items or services reimbursed by any third party payor, including commercial insurers. Further, recently enacted amendments to the Affordable Care Act, among other things, amend the intent requirement of the federal anti-kickback 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 statutes. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid. In addition to the Anti-Kickback Statute, the federal physician self-referral statute, commonly known as the Stark Law, prohibits physicians who have a financial relationship with an entity, including an investment, ownership or compensation relationship, from referring Medicare patients for designated health services, which include clinical pathology services, unless an exception applies. Similarly, entities may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. Many states have their own self-referral laws as well, which in some cases apply to all third party payors, not just Medicare and Medicaid. If a governmental authority were to conclude that we are not in compliance with the Stark Law or state self-referral laws and regulations, our pathology laboratory business could be subject to severe financial consequences, including the obligation to refund amounts billed to third party payors in violation of such laws, civil penalties and potentially also exclusion from participation in government healthcare programs like Medicare and Medicaid. The Stark Law often is enforced through lawsuits brought under the Federal False Claims Act, violations of which trigger significant monetary penalties and treble damages.



Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare providers and suppliers throughout the country for a wide variety of Medicare billing practices, and has obtained multi-million and multi-billion dollar settlements in addition to individual criminal convictions. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and suppliers' compliance with the healthcare reimbursement rules and fraud and abuse laws.

***Health Information Privacy***

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates that perform services for them that involve individually identifiable health information. The HIPAA privacy and security regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the use and disclosure of protected health information by covered entities and their business associates, in addition to setting standards to protect the confidentiality, integrity and security of protected health information.

We have implemented policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law. The privacy and security regulations establish a "floor" and do not supersede state laws that are more stringent. Therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those other countries. The federal privacy regulations restrict our ability to use or disclose patient identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. HIPAA, as amended by HITECH, provides for significant fines and other penalties for wrongful use or disclosure of protected health information in violation of the privacy and security regulations, including potential civil and criminal fines and penalties. If we do not comply with existing or new laws and regulations related to protecting the privacy and security of health information, we could be subject to monetary fines, civil penalties or criminal sanctions. In addition, other federal and state laws that protect the privacy and security of patient information may be subject to enforcement and interpretations by various governmental authorities and courts resulting in complex compliance issues. For example, we could incur damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of confidential health information or other private personal information. If we were to experience a breach of protected health information, we could be subject to significant adverse publicity in addition to possible enforcement sanctions and civil damages lawsuits. Finally, we may be required to incur additional costs related to ongoing HIPAA compliance as may be necessary to address evolving interpretations and enforcement of HIPAA and other health information privacy and security laws, the enactment of new laws or regulations, emerging cybersecurity threats and other factors.



**Research and Development**

Research and development costs relate to our products under development and quality and regulatory costs and are expensed as incurred. During the years ended December 31, 2018 and 2017, we incurred research and development expense of approximately $6.3 million and $5.5 million, respectively. Most of the increase in R&D spending in 2018 was related to the development of a device for intra-operative radiation therapy (IORT) for the treatment of breast and other cancers, for which we

filed a 510(k) application with the U.S. Food and Drug Administration (FDA) in December 2017.

**Employees**

As of December 31, 2018, we had 48 employees, including 45 in the U.S. and three in Israel. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

**Website**

Our filings with the SEC are available free of charge through our website www.sensushealthcare.com. The information on our website is not incorporated by reference into this report.

**Item 1A. RISK FACTORS**

*An investment in our common stock contains a high degree of risk. You should consider carefully the risks and uncertainties described below before making an investment decision. Our business could be harmed if any of these risks, as well as other risks not currently known to us or that we currently deem immaterial, materialize. The trading price of our common stock could decline due to the occurrence of any of these risks, and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and schedules, and other filings with the SEC. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties that could cause our actual results to differ materially from those discussed in this Annual Report on Form 10-K. These risks and uncertainties include the following:*

**Risks Related to our Business**

***We have a history of net losses. If we do not achieve profitability, our financial condition and the value of our common stock could suffer.***

We have a history of net losses. Our historical losses from inception through December 31, 2018 totaled approximately $13.5 million. If our revenue grows more slowly than currently anticipated, or if operating expenses are higher than expected, we may be unable to achieve profitability, our financial condition will suffer and the value of our common stock could decline. Even if we are successful increasing our sales, we may incur losses in the foreseeable future as we continue to research and develop and seek regulatory approvals for our products. If sales revenue from any of our currently cleared products or any additional products that receive marketing clearance from the FDA or approval from other regulatory authorities in the future is insufficient, or if our product development is delayed, we may be unable to achieve profitability. Furthermore, even if we are able to achieve profitability, we may be unable to sustain or increase such profitability on a quarterly or annual basis, which would significantly reduce the value of our common stock.



***If third-party payors do not provide coverage and adequate reimbursement for the use of our products, it is unlikely that our products will be widely used and our revenue will be negatively impacted.***

In the U.S., the commercial success of our existing products and any future products will depend, in part, on the extent to which governmental payors at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for procedures using our products. The existence of coverage and adequate reimbursement for our products and related procedures by government and private payors is critical to market acceptance of our existing and future products. Neither hospitals nor physicians are likely to use our products if they do not receive adequate reimbursement payments for the procedures using our products.

Some private payors in the U.S. may base their reimbursement policies on the coverage decisions determined by the Center of Medicare and Medical Services, or CMS, which administers the Medicare program and works in partnership with state government to administer the Medicaid program. Others may adopt different coverage or reimbursement policies for procedures performed using our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for our products in an amount that supports our selling price, if at all. A Medicare national or local coverage decision denying coverage for any of the procedures performed with our products could result in private and other third-party payors also denying coverage. Medicare (part B) and a number of private insurers in the U.S. currently cover and pay for both non-melanoma skin cancer and keloid treatments using the SRT-100. A withdrawal, or even contemplation of a withdrawal, by CMS, Medicaid or private payors of reimbursements, or any other unfavorable coverage or reimbursement decisions by government programs or private payors, could have a material adverse effect on our business.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be cleared for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems. Our products may not be considered cost-effective by international third-party payors or governments managing healthcare systems. Furthermore, reimbursement may not be available or, if available, third-party payors' reimbursement policies may adversely affect our ability to sell our products profitably. If sufficient coverage and reimbursement are not available for our current or future products, in either the U.S. or internationally, the demand for our products and, consequently, our revenues will be adversely affected.

***Substantially all of our revenue is generated from the sale of our SRT-100 and related products, and any decline in the sales of these products or failure to gain market acceptance of these products will negatively impact our business, financial condition and results of operations.***

We have focused heavily on the development and commercialization of a limited number of products for the treatment of non-melanoma skin cancer and other skin conditions with superficial radiotherapy. From our inception in 2010 through December 31, 2018, substantially all of our revenue has been derived from sales of our SRT-100 product line and related services and ancillary products. Although we intend to introduce new products, we expect most of our 2019 revenue to be derived from or related to sales of our SRT-100 product line. If we are unable to achieve and maintain significantly greater market acceptance of superficial radiotherapy for treatment of non-melanoma skin cancer and other skin conditions, or if we do not achieve sustained positive cash flow, then we will be severely constrained in our ability to fund our operations. In addition, if we are unable to market our SRT-100 product line and ancillary products as a result of a quality problem, shortage of components required for assembly, failure to maintain or obtain regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to the SRT-100 product line and ancillary products, we would lose our only source of revenue, and our business, financial condition and results of operations will be adversely affected.



***We may be unable to manufacture our products in quantities sufficient to meet existing demand levels, which would hinder our ability to effectively commercialize our products and increase revenues.***

The manufacture of medical devices requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, from us and our key suppliers, to scale up the production process to manufacture sufficient quantities at high volume and with satisfactory production yields. Manufacturers of medical devices often encounter difficulties in production, particularly when scaling up initial production. These problems

include difficulties with production costs and yields, quality control and assurance, and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. In July 2010, we entered into a manufacturing agreement with an unrelated third party for the manufacturing and production of the SRT-100 in accordance with our specifications. We continue to do business with the manufacturer pursuant to this agreement, although we or the manufacturer may terminate the agreement upon 90 days' written notice or upon at least 60 days' notice prior to the end of each additional one-year renewal period. As discussed elsewhere in this Annual Report on Form 10-K, we are in the process of adding another contract manufacturer and are exploring the possibility of bringing certain manufacturing capabilities in-house. However, if eventually implemented, our plan to bring the manufacturing function in-house may not be successful and we may be unable to maintain a relationship with our current manufacturer or establish a relationship with another manufacturer on favorable terms, if at all.

Consequently, we may be able to continue to efficiently manufacture our products in sufficient quantities to meet projected demand or to establish sufficient worldwide inventory to fully support our distribution network. Any of these results could cause us to be unable to effectively commercialize our products or increase revenue, adversely affecting our business, financial condition, results of operations and the value of our common stock.

***We have a single preferred supplier for the x-ray tubes and other major components used in our products and the loss of this preferred supplier could adversely affect us.***

We have a single preferred supplier for the x-ray tubes and other major components used in our products. Although other suppliers exist in the market, we believe that our preferred supplier's products are of a superior quality. The loss of these preferred suppliers, or their inability to supply us or our third party manufacturer with adequate components could hinder our ability to effectively produce our products to meet existing demand levels, especially if we were unable to timely procure them from other suppliers in the market, which could adversely affect our ability to commercialize our products and increase our revenues.

***We may be unable to retain and develop our U.S. sales force and non-U.S. distributors, which would adversely affect our ability to meet our revenue targets and other goals.***

As we launch products, increase current sales efforts and expand into new geographic areas, we will need to retain, grow and develop our direct sales personnel, distributors and agents. There is significant competition for sales personnel experienced in relevant medical device sales. In addition, the training process is lengthy because it requires significant education for new sales representatives to achieve an acceptable level of clinical competency with our products. Upon completion of training, sales representatives typically require lead time in the field to develop or expand their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. If we are unable to attract, motivate, develop, and retain a sufficient number of qualified sales personnel, or if the sales representatives do not achieve the productivity levels expected, our revenue will not grow as expected, and our financial performance will suffer.

In addition, we may not succeed in entering into and maintaining productive arrangements with an adequate number of distributors outside of the U.S. that are sufficiently committed to selling our products in international markets. The establishment and maintenance of a distribution network is expensive and time consuming. Even if we engage and maintain suitable relationships with an adequate number of distributors, they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our products. Moreover, if our sales force and distributors are unable to attract and retain new customers, we may be unable to achieve our expected growth, and our business could suffer. Furthermore, some of our distributors may market or sell the products of our competitors. In these cases, the competitors may have the ability to influence the products that our distributors choose to market and sell, for example, by offering higher commission payments, or by convincing the distributors to terminate their relationships with us, carry fewer of our products or reduce their sales and marketing efforts for our products. Any of the foregoing would hinder our ability to meet our revenue targets and other goals.



***The future worldwide demand for our current products and our future products is uncertain. Our current products and our future products may not be accepted by hospitals, physicians or patients, and may not become commercially successful.***

Physicians and hospitals may not perceive the benefits of our products and may be reluctant or unwilling to adopt our products as a treatment option, particularly in light of existing treatment options, such as Mohs surgery or high dose rate brachytherapy. Additionally, physicians and hospitals may not be aware of the significant advances in technology associated with superficial radiation therapy compared to older technology that was previously used with orthovoltage. While we believe that our products are an efficient and less invasive alternative to other treatments of non-melanoma skin cancer and other skin conditions, physicians who are accustomed to using other modalities to treat patients with either non-melanoma skin cancer, keloids or other skin conditions may be reluctant to adopt broad use of our superficial radiotherapy products.

We must grow markets for our products through physician education and awareness programs. Publication in peer-reviewed medical journals of results from studies using our products will be an important consideration in their adoption by physicians and in reimbursement decisions of third-party payors. The process of publication in leading medical journals is subject to a peer-review process. Peer reviewers may not consider the results of studies of our products and any future products sufficiently novel or worthy of publication. Failure to have studies of our products published in peer reviewed journals may adversely affect adoption of our products.

Educating physicians and hospitals on the benefits of our products and advancements in superficial radiation technology requires a significant commitment by our marketing team and sales organization. Our products may not become widely accepted by physicians and hospitals. If we are unable to educate physicians and hospitals about the advantages of our products, do not achieve significantly greater market acceptance of our products, do not gain momentum in our sales activities, or fail to significantly grow our market share, we will be unable to grow our revenue, and our business and financial condition will be adversely affected.

***We are in a highly competitive market segment, which is subject to rapid technological change. If our competitors are able to develop and market products that are more effective, less costly, easier to use or otherwise more attractive than any of our products, our business will be adversely impacted.***

The medical device industry is highly competitive and subject to technological change. In the arena for technology and products for use in the treatment of non-melanoma skin cancer and other skin conditions, we have three primary competitors, one of which operates in the superficial radiotherapy space largely in the European market, and the other two of which operate in the brachytherapy space in both the U.S. and internationally. While we believe our SRT-100 and related products currently have certain competitive advantages over the products offered by these competitors, our success depends, in part, upon our ability to maintain this competitive position. If these competitors improve their existing products, develop new products, or expand their operations, we may be unable to maintain our competitive advantages over these competitors.

Furthermore, new competitors, including companies larger than us, may enter the market in the future and may offer products with similar or alternative functionalities. These companies may enjoy several advantages relative to us, including:

- greater financial and human resources for product development, sales and marketing;
- greater name recognition;
- long-established relationships with physicians and hospitals;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- more established distribution channels and sales and marketing capabilities; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing cleared products.

Hospitals, physicians and investors may not view our products as competitive with other products that are marketed and sold by new competitors, including much larger and more established companies. Our competitors may develop and patent processes or products earlier than we do, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective, more convenient or less expensive products or technologies that render our technology or products obsolete or less competitive. If our existing or new competitors are more successful than us in any of these matters, our business may be harmed.

***Our customers are concentrated in the U.S. and China, and economic difficulties or changes in the purchasing policies or patterns of our customers in these countries could have a significant impact on our business and operating results.***

Substantially all of our 2018 and 2017 sales were made to customers located in the U.S., however in previous years significant sales were made to customers located in China. For the years ended December 31, 2018 and 2017, approximately 1% and 2%, respectively, of our product sales were to Chinese customers, with substantially the remainder of our sales to customers in the U.S. Additionally, a single customer in the U.S. accounted for approximately 71% and 59% of revenues for the years ended December 31, 2018 and 2017, respectively. Because of our geographic and customer concentrations, our revenue could fluctuate significantly due to changes in economic conditions, the use of competitive products, or the loss of, reduction of business with, or less favorable terms within, these countries or this customer. A reduction or delay in orders for our products from these countries and this customer could materially harm our business and results of operations.

***Our future success depends on our ability to develop, receive regulatory approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner, and if we do not do so, our results of operations will suffer.***

It is important to our business that we continue to build a pipeline of product offerings for the treatment of non-melanoma skin cancer and other skin conditions to remain competitive. Consequently, our success will depend in part on our ability to develop and introduce new products. However, we may be unable to successfully maintain our regulatory clearance for existing products, or develop, obtain and maintain regulatory clearance or approval for product enhancements, or new products, or these products may not be accepted by physicians or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products with data;
- obtain the necessary regulatory approvals for new products or product enhancements;
- comply fully with U.S. Food and Drug Administration and applicable foreign government agencies' regulations on marketing of new devices or modified products;
- provide adequate training to potential users of our products; and
- receive coverage and adequate reimbursement for procedures performed with our products.

If we do not develop new products or product enhancements and obtain regulatory approval in time to meet market demand, if there is insufficient demand for these products or enhancements, or if competitors introduce new products with enhanced functionalities that are superior to those of ours, then our results of operations will suffer.

***Our products may become obsolete prior to the end of their anticipated useful lives, and we may be required to dispose of existing inventory or write off the value or accelerate the depreciation of these assets, each which would materially and adversely impact our results of operations.***

We focus on continual product innovation and product improvement. While we believe this provides a competitive edge, it also creates a risk that our products will become obsolete prior to the end of their anticipated useful lives. If we introduce new products or next-generation products prior to the end of the useful life of a prior generation, we may be required to dispose of existing inventory, or write off the value of these assets, each of which would materially and adversely impact our results of operations.



***Our success is dependent in large part on our being an early re-entrant into the market for our proprietary superficial radiotherapy systems, and if one or more competitors join us in the market, our marketing efforts and ability to compete would be materially and adversely affected.***

Our success is dependent in large part on our being an early re-entrant into the market for our proprietary superficial radiotherapy systems. If one or more competitors join us in the market, the increased competition would require us to devote substantial additional resources to our marketing efforts, and our ability to compete may be severely impaired.

***Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.***

The sale and shipment of our products across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, and anti-boycott laws, as well as export control laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities. Any of the foregoing would adversely impact our results of operations and financial condition.

Our international operations and our international distributors expose us to risks inherent in operating in foreign jurisdictions. These risks include, without limitation:

- difficulties in enforcing or defending intellectual property rights;
- pricing pressure that we may experience internationally;
- a shortage of high-quality sales people and distributors;
- third-party reimbursement policies that may require some of the patients who are treated with our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;
- disadvantage to competition with established business and customer relationships;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- potentially adverse tax consequences;
- laws and business practices favoring local companies;
- difficulties in maintaining consistency with our internal guidelines;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit

continued business with the sanctioned country, company, person or entity; and
- the imposition of new trade restrictions.

If any of these events or circumstances were to occur, our sales in foreign countries would be harmed and our results of operations would suffer.



***Our U.S. business could be adversely affected by changes in international trade regulation.***

Both the Trump Administration and certain members of the U.S. Congress have indicated that they may seek to impose importation tariffs on products from certain countries such as China and Mexico or to impose additional taxes on imported goods generally. Certain countries have publicly stated that they would respond in-kind to any such action by the U.S. The Trump Administration recently imposed tariffs on solar panels and washing machines. Any future escalation of protectionist trade measures could increase the prices of products, components and supplies that we source internationally, as well as adversely affect our ability to sell our products in foreign markets. In addition, the Trump Administration has appointed and employed many new public officials into positions of authority in the U.S. Federal government dealing with the healthcare industries that may potentially have a negative impact on the prices and the regulatory pathways for certain healthcare products such as those developed, marketed and sold by us. Such changes in the regulatory pathways could adversely affect and or delay our ability to market and sell our products in the U.S. and internationally.

***Our operating results may vary significantly from quarter to quarter, which may negatively impact the value of our securities.***

Our quarterly revenues and results of operations may fluctuate due to the following reasons, among others:

- physician and hospital acceptance of our products;
- the timing, expense and results of research and development activities, and obtaining future regulatory approvals;
- fluctuations in expenses associated with expanding operations;
- the introduction of new products and technologies by competitors;
- sales representatives' productivity;
- supplier, manufacturing or quality problems with products;
- the timing of stocking orders from distributors;
- changes in our pricing policies or in the pricing policies of competitors or suppliers; and
- changes in third-party payors' reimbursement policies.

Because of these and other related or similar factors, it is likely that in some future period our operating results will not meet expectations. Failure to meet or exceed analyst expectations could cause a decrease in the trading price of our securities.

***We may be unable to attract and retain highly qualified personnel, which could adversely and materially affect our competitive position.***

Our future success depends on our ability to attract and retain our executive officers and other key employees. We may be unable to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among companies in the medical device business and related industries, particularly in the South Florida area where we are headquartered. The medical device industry has experienced a high rate of turnover of management personnel in recent years. Consequently, we could have difficulty attracting or retaining experienced personnel and may be required to spend significant time and expend significant financial resources in our employee recruitment and retention efforts. Many of the other medical device companies with which we compete for qualified personnel have greater financial and other resources and risk profiles different from ours. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we may offer. If we are unable to attract and retain the necessary personnel to accomplish our business objectives, we may have difficulty implementing our business strategy and achieving our business objectives.

***Product liability claims could damage our reputation and adversely affect our business.***

The design, manufacture and marketing of medical devices each carry an inherent risk of product liability claims and other damage claims. In addition to the exposure we may have for defective products, physicians may misuse our products or use improper techniques, regardless of how well trained, potentially leading to injury and an increased risk of product liability. A product liability or other damages claim, product recall or product misuse could require us to spend significant time and money in litigation, regardless of the ultimate outcome, or to pay significant damages and could seriously harm our business.



We maintain liability insurance coverage that management believes to be reasonable based on our business and operations; however, our insurance may not be sufficient to cover all claims made against us. Our insurance policies generally must be renewed on an annual basis. We may be unable to maintain or increase insurance on acceptable terms or at reasonable costs. A successful claim brought against us in excess, or outside of, our insurance coverage could seriously harm our financial condition or results of operations.

***We may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.***

Our operations have consumed substantial amounts of cash since inception, and we anticipate that our expenses will increase as we continue to grow our business. We may need to seek additional capital in the future. Our growth will depend, in part, on our ability to develop variations of the SRT-100 and other products, and related technology complementary to our products. Our existing financial resources, including our existing revolving line of credit, may not allow us to conduct all of the activities that we believe would be beneficial for our future growth.

We may need to seek funds in the future. Our existing revolving line of credit restricts our ability to incur certain indebtedness or permit certain encumbrances on our assets without the prior written consent of the lender. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities or meet our debt and other contractual obligations, and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively.

Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the results of commercialization efforts for products;
- the need for additional capital to fund development programs;
- the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property;
- the establishment of high-volume manufacturing and increased sales, marketing and distribution capabilities; and
- success in entering into collaborative relationships with other parties.

We may be unable to raise funds on favorable terms, or at all, and either case would materially and adversely affect our ability to implement our strategy and meet our goals.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders' ownership interest will be diluted. Moreover, the

terms of newly issued securities may include liquidation or other preferences that adversely affect common stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring distributions or dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or products or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to declare dividends on our common stock and to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

***Our revolving credit facility imposes substantial restrictions on us, some of which could hinder our ability to conduct our operations effectively or otherwise in accordance with our business plan.***

Our revolving credit facility contains a number of negative covenants that require us to seek the lender's prior written consent in order to conduct certain activities. For example, we may not, without the prior written consent of the lender:

- Sell or otherwise transfer all or any part of our business or property, except for transfers in the ordinary course of business or as otherwise permitted by the facility agreement;
- Change the nature of our business, liquidate or dissolve, undergo a change in management;



- Add any new offices or business locations, including warehouses;
- Change our jurisdiction of organization, our organizational structure or type, our legal name or any organizational number assigned to us;
- Merge or consolidate with any other person or entity or acquire all or substantially all of the capital stock or property of another person or entity;
- Create, incur or be liable for any indebtedness other than as permitted by the facility agreement;
- Create, incur, or suffer any lien on any of our property (including receivables) other than as permitted by the facility agreement;
- Maintain any operating or deposit or security accounts other than with the lender or any of its affiliates;
- Pay any dividends or make any distribution or payment or redeem, retire or purchase any capital stock, except that we may pay dividends solely in common stock; or
- Directly or indirectly make any investment, including, without limitation, by the formation of any subsidiary, other than as permitted by the facility agreement.

In the event we wish to conduct any of the foregoing activities and the lender refuses to provide its prior written consent, our ability to conduct our operations effectively and in accordance with our business plan could be materially and adversely affected.

***If we fail to properly manage our anticipated growth, our business could suffer.***

Our strategy involves substantial growth. If we experience periods of rapid growth and expansion, our limited personnel, operational infrastructure and other resources could be significantly strained. In particular, the possible internalization of manufacturing, and continued expansion of our direct sales force in the U.S. will require significant management, financial and other supporting resources. In addition, in order to manage expanding operations, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our goals. To achieve our revenue goals, we must successfully increase production output to meet projected customer demand. We may be unable to increase output on the timeline anticipated, if at all. Also, we may in the future experience difficulties with production yields and quality control, component supply, and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any delay or increased expense could adversely affect our ability to increase revenues.

***Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.***

In an effort to reduce costs, many hospitals or physicians within the U.S. and abroad are members of group purchasing organizations and integrated delivery networks. Group purchasing organizations and integrated delivery networks negotiate pricing arrangements with medical device companies and distributors and offer the negotiated prices to affiliated hospitals, physicians and other members. Group purchasing organizations and integrated delivery networks typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the group purchasing organizations and integrated delivery networks contracting processes, we may be unable to obtain or maintain contract positions with major group purchasing organizations and integrated delivery networks. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability.

While having a contract with a group purchasing organizations or integrated delivery networks for a given product category can facilitate sales to members of that group purchasing organizations or integrated delivery networks, expected sales levels may not be achieved, as sales are typically made pursuant to purchase orders. Even when a provider is the sole contracted supplier of a group purchasing organization or integrated delivery network for a certain product category, members of the group purchasing organization or integrated delivery network generally are free to purchase from other suppliers. Furthermore, group purchasing organizations and integrated delivery networks contracts typically are terminable without cause by the group purchasing organizations or integrated delivery networks upon 60 to 90 days' notice. Accordingly, even if we obtain contracts with any group purchasing organizations or integrated delivery networks, the members of these groups may choose to purchase from our competitors due to the price or quality offered by competitors, which could result in a decline in our sales and profitability.



***We depend on information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.***

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. Our information technology systems could be vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any successful attacks could result in the theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information or disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent, and our systems could be the target of malware and other cyber-attacks. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats.

However, these measures and efforts may not prevent interruptions or breakdowns, and we may otherwise fail to maintain or protect our information technology systems and data integrity effectively. Furthermore, we may fail to anticipate, plan for or manage significant disruptions to our systems. If any of the foregoing were to occur, our competitive position could be harmed, we could lose existing customers, have difficulty preventing, detecting and controlling fraud, have disputes with customers, specialist physicians and other healthcare professionals, have regulatory sanctions or penalties imposed, incur expenses or lose revenues as a result of a data breach or theft of intellectual property or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition or cash flows.

***Consolidation in the healthcare industry could adversely affect our future revenues and operating income.***

The medical technology industry has experienced a significant amount of consolidation, resulting in companies with greater market presence. Health care systems and other health care companies are also consolidating, resulting in greater purchasing power for these companies. As a result, the disruption in the healthcare industry caused by consolidation may lead to further competition among medical device suppliers to provide goods and services, which could adversely affect our future revenues and operating income.

***We may engage in acquisitions, mergers, strategic alliances, and joint ventures that could result in final results that are different than expected.***

In the normal course of business, we engage in discussions relating to possible acquisitions, equity investments, mergers, strategic alliances, and joint ventures. Such transactions are accompanied by a number of risks, including the use of significant amounts of cash, potentially dilutive issuances of equity securities, incurrence of debt on potentially unfavorable terms as well as impairment expenses related to goodwill and amortization expenses related to other intangible assets, the possibility that we may pay too much cash or issue too many of our shares as the purchase price for an acquisition relative to the economic benefits that we ultimately derive from such acquisition, and various potential difficulties involved in integrating acquired businesses into our operations.

If we do not realize the expected benefits of such transactions, our financial position, results of operations, cash flows and stock price could be negatively impacted.

**Risks Related to our Regulatory Environment**

***We are subject to various federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with these laws and regulations could have a material adverse effect on our business.***

Our operations are, and will continue to be, directly and indirectly affected by various federal, state and foreign healthcare laws, including, but not limited to, those described below.

- Federal Anti-Kickback Statute (42 U.S. Code §1320a-7b), which prohibits any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the referring, ordering, purchasing or leasing of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs.



- Federal "Sunshine" (42 U.S. Code §1320a-7h) law, which requires us to track and report annually to CMS information related to certain payments and other "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and to report annually to CMS ownership and investment interests held by physicians, and their immediate family members. We are also subject to similar foreign "sunshine" laws or codes of conduct, which vary country by country.

- Federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim to, or the knowing use of false records or statements to obtain payment from, or approval by, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act (31 U.S. Code §3729-3733), it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Many of the physicians that use our products will file for reimbursement from governmental programs such as Medicare and Medicaid. As a result, we may be subject to the False Claims Act if we knowingly "cause" the filing of false claims.

- Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, statute, which, among other things, created federal criminal laws that prohibit knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services.

Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and applicable implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on entities subject to the law, such as health plans, clearinghouses, and healthcare providers and their business associates. Internationally, substantially every jurisdiction in which we operate has established its own data security and privacy legal framework with which we must comply, including the Data Protection Directive 95/46/EC and national implementation of the Directive in the member states of the European Union.

Many states have also adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers, as well as laws that restrict our marketing activities with healthcare professionals and entities, and require us to track and report payments and other transfers of value, including consulting fees, provided to healthcare professionals and entities. Some states mandate implementation of compliance programs to ensure compliance with these laws. Additionally, certain states require a certificate of need prior to the installation of a radiation device, such as the SRT-100. We are also subject to foreign fraud and abuse laws, which vary by country.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, individual imprisonment, contractual damages, reputational harm, exclusion from governmental healthcare programs, and the curtailment or restructuring of our operations. Any of the foregoing could adversely affect our ability to operate our business and our financial results.



***Our products are subject to extensive governmental regulation that could make it more expensive and time consuming for us to introduce new or improved products.***

Our products must comply with regulatory requirements imposed by the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services and other governmental agencies in the U.S., and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, an extensive agency review process, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. If we execute on our plans to move our manufacturing function in-house, we will also be subject to additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potential hazardous substances. Some of the most important requirements applicable or potentially applicable to us include:

- U.S. Food and Drug Administration Regulations (Title 21 CFR, Parts 801, 803, 806, 807 and 820);
- EU CE marking of conformity requirements depicted within the MDD (Directive 90/425/EEC);
- Health Canada requirements (SOR/98-282);
- Medical Device Quality Management System requirements (ISO 13485:2003);
- Occupational Safety and Health Administration requirements;
- China CFDA requirements; and

- Other similar quality, regulatory and statutory requirements in foreign jurisdictions in which we currently market or plan to market our products in the future.

Additionally, due to the nature of our products as radiation producing medical devices, we are also subject to certain state laws and regulations related to the sale of our products. Although we have taken steps to ensure our compliance with such state laws and regulations, our failure to fully comply with these requirements could result in fines or penalties and could also adversely affect our ability to sell our products.

Government regulation may impede our ability to the manufacture our existing and future products. Government regulation also could delay the marketing of new products for a considerable period of time and impose costly procedures on activities. The U.S. Food and Drug Administration and other regulatory agencies may not clear or approve any future products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, these approvals could negatively impact the marketing of any future products and reduce our product revenues. Regulatory bodies may review products once they are on the market and determine that they do not satisfy applicable regulatory requirements. Failure to comply with requisite requirements may lead to European Economic Area regulatory bodies ordering the suspension or withdrawal of products from the European Economic Area market or, as discussed below, notified bodies withdrawing certificates of conformity for devices or the underlying quality systems.

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways.

***Product deficiencies could result in field actions, recalls, substantial costs or write-downs; which could lead to the delay or termination of ongoing trials, if any, and harm our reputation, business or financial results.***

Our products are subject to various regulatory guidelines and involve complex technologies. The U.S. Food and Drug Administration and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use or if a deficiency in a device is found or suspected.

Identified quality problems, such as failure of critical components, or the failure of third parties to supply us with sufficient conforming quantities of these products or components, could impact the availability of our products in the marketplace or lead to adverse clinical events. In addition, product improvements or product redundancies could result in scrapping or expensive rework of products, and our business, financial condition or results of operations could suffer as a result. Product complaints, quality issues and necessary corrective and preventative actions could result in communications to customers or patients, field actions, require the scrapping, rework, recall or replacement of products, result in substantial costs or write-offs, or harm our business reputation and financial results. Further, these events could adversely affect our relationships with our customers or affect our reputation, which could materially adversely affect our earnings, results and financial viability.

A future field action or recall announcement could harm our reputation with customers, negatively affect our sales, and subject us to U.S. Food and Drug Administration (or similar governmental authority) enforcement actions. Moreover, depending on the corrective action we take to redress a product's deficiencies or defects, the U.S. Food and Drug Administration (or similar governmental authority) may require, or we may decide, that we will need to obtain new approvals or clearances for the product before we market or distribute the corrected product. Seeking these approvals or clearances may delay our ability to replace the recalled products in a timely manner. If we do not adequately address problems associated with our products, we may face additional regulatory enforcement action, including U.S. Food and Drug Administration (or similar governmental authority) warning letters, product seizures, injunctions, administrative penalties, or civil or criminal fines.



Any identified quality issue can both harm our business reputation and result in substantial costs and write-offs, which in either case could materially harm our business and financial results.

***The off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, or result in costly investigations and regulatory agency sanctions under certain circumstances.***

The products we currently market in the U.S. have been cleared by the U.S. Food and Drug Administration for specific indications. Our clinical support staff and marketing and sales force have been trained not to promote our products for uses outside of the cleared indications for use, known as "off-label uses." However, if a physician uses our products outside the scope of the cleared indications, there may be increased risk of injury to patients. Furthermore, the use of our products for indications other than those cleared by the U.S. Food and Drug Administration may not effectively treat the conditions associated with the off-label use, which could harm our reputation in the marketplace among physicians and patients, adversely affecting our operations.

If the U.S. Food and Drug Administration determines that our promotional materials or training constitute promotion of an off-label or other improper use, it could request that we modify our training or promotional materials, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Any of these events could significantly harm our business and results of operations.

The advertising and promotion of our products is subject to European Economic Area Member States governing the advertising and promotion of medical devices. In addition, voluntary European Union and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on promotional activities with healthcare professionals. These regulations or codes may limit our ability to affectively market our products, or we could run afoul of the requirements imposed by these regulations, causing reputational harm, imposing potentially substantial costs, and adversely affecting our operations as a result.

***We are required to comply with medical device reporting requirements and must report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions.***

Under the U.S. Food and Drug Administration medical device reporting regulations (21 CFR 803), medical device manufacturers are required to submit information to the U.S. Food and Drug Administration when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the European Economic Area are legally bound to report any serious or potentially serious incidents involving devices they produce or sell (MEDDEV 2.12-1) to the Competent Authority in whose jurisdiction the incident occurred through the European Vigilance process.

If an event subject to medical device reporting requirements occurs, we will need to comply with the reporting requirements, which would adversely affect our reputation and subject us to actions by regulatory authorities, such as ordering recalls, imposing fines, or seizing the affected products. Furthermore, any corrective action, whether voluntary or involuntary, will require the dedication of time and capital and will distract management from operating our business. Any of the foregoing would further harm our reputation and financial results.

***Healthcare policy changes may have a material adverse effect on our business.***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, included, among other things, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions, effective January 1, 2013. This excise tax imposed a significant increase in the tax burden on the medical device industry. This excise tax was repealed in 2018. Other elements of this law, including comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and may result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

Other healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the reimbursement received for procedures utilizing our products. In addition, other legislative changes have been proposed and adopted since the law discussed above was enacted that may adversely affect our revenues. Changes to existing laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our business and financial operations. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to increase revenue, attain profitability, or commercialize our devices. In addition, other legislative changes may be enacted or existing regulations, guidance or interpretations may be changed, each of which may adversely affect our operations.

**Risks Related to our Intellectual Property**

***If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to competitors and be unable to operate our business profitably.***

Our success significantly depends on our ability to protect our proprietary rights to the technologies used in our products. We rely on the patent protection of two U.S. patents and two foreign patents which we have acquired, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. We also have patent applications currently pending and in the process of being submitted. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, some or all of our pending patent applications or any future pending applications may be unsuccessful. The U.S. Patent and Trademark Office may deny or require significant narrowing of claims in our pending patent applications or future patent applications, and patents issued as a result of these patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the U.S. Patent and Trademark Office. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in our issued patents. Third parties may successfully challenge our issued patents and those that may be issued in the future, which would render these patents invalidated or unenforceable, and which could limit our ability to stop competitors from marketing and selling related products. In addition, our pending patent applications include claims to aspects of our products and procedures that are not currently protected by issued patents, and third parties may successfully patent those aspects before us or otherwise challenge our rights to these aspects.

Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products. Although we have entered into confidentiality agreements and intellectual property assignment agreements with certain of our employees, consultants and advisors in order to protect our intellectual property and other proprietary technology, these agreements may not be enforceable or may not provide meaningful protection for trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. In addition, we have not sought patent protection in all countries where we sell our products. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. Furthermore, the laws of some foreign countries may not protect intellectual property rights to the same extent as the laws of the U.S., if at all.



In the event a competitor infringes upon one of our patents or other intellectual property rights, enforcing those patents and rights may be difficult and time consuming. Even if successful, litigation to defend our patents against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources to defend our patents against challenges or to enforce our intellectual property rights, any of which would adversely affect our ability to compete and our business operations as a result.

***If our trademarks or trade names are not adequately protected, then we may be unable to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to infringe other marks. We may be unable to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in markets of interest. If our trademarks are challenged, infringed upon, circumvented, or declared generic or infringing, or if we are unable to establish name recognition based on our trademarks and trade names, then we may be unable to compete effectively and our business may be adversely affected.

***The medical device industry is characterized by extensive patent litigation, and if we become subject to litigation, it could be costly, result in the diversion of management's attention, require us to pay significant damages or royalty payments, or prevent us from marketing and selling our existing or future products.***

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Determining whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that their products, the components of those products, the methods of using those products, or the methods we employ in processing those products are covered by U.S. or foreign patents held by them. In addition, they may claim that their patents have priority over us because their patents were issued first. Because patent applications can take many years to issue, our products that currently do not infringe on existing issued patents may later infringe on patents that are pending now or in the future. Our products might also inadvertently infringe on currently issued patents. As the number of participants in the market for skin cancer and general oncology devices and treatments increases, the possibility of patent infringement claims against us increases. Any infringement claims, litigation or other proceedings would place a significant strain on our financial resources, divert the attention of management from the core business and harm our reputation.

A larger more established company could allege that we infringed its patent, and that we owe royalty payments on sales of certain products as a result. Any claim against us, even without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from the core business and harm our reputation. If the appropriate authority upholds the company's patent as valid and enforceable and finds that we infringed on the patent, we could be required to pay substantial damages, including treble, or triple, damages and royalties if an infringement is found to be willful, and we could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. A license may not be available on reasonable terms, if at all, and we may be unable to redesign products in a way that would not infringe those patents. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, either of which could have a significant adverse effect on our business, financial condition and results of operations.

Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, or using products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, licensing, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;

- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; or
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive or infeasible.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

We may indemnify our customers and international distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of customers or distributors or may be required to obtain licenses for the products they use, each which would adversely affect our operations. If we cannot obtain all necessary licenses on commercially reasonable terms, customers may be forced to stop using our products, which would materially and adversely affect our business.

***We may be subject to damages resulting from claims that we, our employees or independent distributors have wrongfully used or disclosed alleged trade secrets of competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors. Many of our independent distributors sell, or in the past have sold, products of competitors. We may be subject to claims that we, our employees or independent distributors have inadvertently or otherwise used or disclosed the trade secrets or other proprietary information of our competitors. In addition, we have been and may in the future be subject to claims that we caused an employee or independent distributor to break the terms of his or her non-competition agreement or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending these claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize products, which could have an adverse effect on our business, financial condition and results of operations.

***Adverse outcomes in litigation or similar proceedings could adversely impact our business.***

We may in the future be, named as a party to litigation or other similar legal proceedings. Adverse outcomes in any or all of these proceedings could result in monetary damages or injunctive relief that could adversely affect our ability to continue conducting our business. If an unfavorable final outcome in any such matter becomes probable and reasonably estimable, our financial condition could be materially and adversely affected.

**Risks Related to the Ownership of our Securities**

***Limited trading activity for shares of our common stock and warrants may contribute to price volatility.***

While our common stock and warrants are listed and traded on the Nasdaq Capital Market, there has been limited trading activity in our securities. Due to the limited trading activity of our securities, relativity small trades may have a significant impact on the price of our securities.



***With two exceptions, we have never declared or paid cash dividends on our common stock and do not anticipate paying dividends in the foreseeable future. As a result, you must rely on price appreciation of our common stock for a return on your investment in the foreseeable future.***

Except for a required tax distribution in 2014 in the aggregate amount of $45,421, and a one-time payment in the aggregate amount of approximately $2.6 million paid to former holders of our LLC units with a preferred return in 2016 (prior to our conversion to a corporation), we have never declared or paid cash dividends on our common stock. We currently expect to retain our funds and future earnings to support the operation, growth and development of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a return on your investment in the near future will occur only if our share price appreciates. Our securities prices may not appreciate in value or maintain the prices at which you purchased our securities, and in either case, you may not realize a return on investment or could lose all or part of your investment in our securities.

Furthermore, any future determination to declare cash dividends will be made at the discretion of our board of directors and will be subject to compliance with applicable laws and covenants under any future credit facilities, which may restrict or limit our ability to pay dividends. For example, our current revolving line of credit restricts our ability to pay dividends or make any distributions or payments or redeem, retire or purchase any capital stock without the prior written consent of the lender, provided that we may pay dividends solely in common stock. Also, the form, frequency and amount of dividends will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant. We may not pay dividends as a result of any of the foregoing, and in these cases, you will need to rely on price appreciation of our common stock for a return on your investment.

***General stock market volatility could result in significant declines in the trading price of our securities, and you could lose all or a substantial part of your investment.***

Stock markets have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our securities. In addition, limited trading volume of our securities may contribute to its future volatility. Price declines in our securities could result from general market and economic conditions, some of which are beyond our control, and a variety of other factors, including any of the risk factors described in this Annual Report on Form 10-K. These broad market and industry factors may harm the market price of our securities, regardless of our operating performance, and could cause you to lose all or part of your investment in our securities since you might be unable to sell your securities at or above the price you paid. Factors that could cause fluctuations in the market price of our securities include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of medical device company stocks;
- changes in operating performance and stock market valuations of other medical device companies generally, or those in our industry in particular;
- sales of our securities by us or our stockholders;
- failure of securities analysts to initiate or maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our results of operations or fluctuations in our results of operations;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;

- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.



***We are both an "emerging growth company" and a "smaller reporting company" and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies but not to "emerging growth companies," including, but not limited to:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- 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 will remain an emerging growth company until the earlier of (1) December 31, 2021, (2) the last day of the year in which (a) we have total annual gross revenue of at least $1 billion, or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30$^{th}$, and (3) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period. Investors may find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

Under the Jumpstart Our Business Startups Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are a "smaller reporting company," meaning that our outstanding common stock held by nonaffiliates had a value of less than $250 million at the end of our most recently completed second fiscal quarter. Thus, even if we are no longer an emerging growth company, as a smaller reporting company, we could take advantage of certain reduced governance and disclosure requirements, including not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting. As a result, investors and others may be less comfortable with the effectiveness of our internal controls and the risk that material weaknesses or other deficiencies in internal controls go undetected may increase. In addition, as a smaller reporting company, we take advantage of our ability to provide certain other less comprehensive disclosures in our SEC filings, including, among other things, providing only two years of audited financial statements in annual reports and simplified executive compensation disclosures. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects, as the information we provide to stockholders may be different from what one might receive from other public companies in which one holds shares.



***Our executive officers, directors and principal stockholders may exert control over us and may exercise influence over matters subject to stockholder approval.***

Our executive officers and directors, together with their respective affiliates, beneficially owned approximately 33% of our outstanding common stock as of March 8, 2019. Accordingly, these stockholders, if they act together, may exercise substantial influence over matters requiring stockholder approval, including the election of directors and approval of corporate transactions, such as a merger. This concentration of ownership could have the effect of delaying or preventing a change in control or otherwise discourage a potential acquirer from attempting to obtain control over us, which in turn could have a material adverse effect on the market value of our common stock.

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

The trading market for our securities will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We may be unable to attract or sustain coverage by well-regarded securities and industry analysts. If either none or only a limited number of securities or industry analysts cover us or our business, or if these securities or industry analysts are not widely respected within the general investment community, the trading price for our securities would be materially and negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who cover us or our business downgrade our securities or publish inaccurate or unfavorable research about us or our business, the price of our securities would likely decline. If one or more of these analysts cease coverage of us or our business, or fail to publish reports on us or our business regularly, demand for our securities could decrease, which might cause the price of our securities and trading volume to decline.

***Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current directors and management.***

Provisions of Delaware law (where we are incorporated), our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- requiring supermajority stockholder voting to effect any merger or sale of all or substantially all of our stock our assets;
- eliminating the ability of stockholders to call and bring business before special meetings of stockholders;

- prohibiting stockholder action by written consent;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- dividing our board of directors into three classes so that only one third of our directors will be up for election in any given year; and
- providing that our directors may be removed only by the affirmative vote of at least 75% of our then-outstanding common stock and only for cause.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging takeover attempts that could have resulted in a premium over the market price for shares of our common stock.

These provisions will apply even if a takeover offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our board of directors determines is not in our and our stockholders' best interests and could also affect the price that some investors are willing to pay for our common stock.



***Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the action in other jurisdictions, which could harm our business and financial condition.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired and investors' views of us or our business could be harmed, resulting in a decrease in value of our common stock.***

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in our internal controls. In addition, we are required to furnish a report by management on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company, which may be up to five full years following the date of our IPO, or the date we no longer qualify as a smaller reporting company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require us to incur substantial accounting expense and expend significant management efforts. If we are unable to comply with the requirements of Section 404 in a timely manner, or we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to implement our business plan successfully and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new, operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors when required under Section 404 of the Sarbanes-Oxley Act. Moreover, we may not implement and maintain adequate controls over our financial processes and reporting in the future. Even if we were to conclude, and, when required, our auditors were to concur, that our internal control over financial reporting provided reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, because of our inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements or omissions.

***Our operations may be impaired if our information technology systems fail to perform adequately or if we are the subject of a data breach or cyberattack.***

Our information technology systems are critically important to operating our business efficiently. We rely on our information technology systems to manage our business data, communications, employee information, and other business processes. We outsource certain business process functions to third-party providers and similarly rely on these third parties to maintain and store confidential information on their systems. The failure of these information technology systems to perform as we anticipate could disrupt our business and could result in transaction errors, processing inefficiencies, and the loss of sales and customers, causing our business and results of operations to suffer.



Although we protect our information technology systems, we have experienced varying degrees of cyber-incidents in the normal conduct of our business, including viruses, worms, phishing and other malicious activities. Although there have been no serious consequences to date, such breaches could result in unauthorized access to information including customer, supplier, employee, or other company confidential data. We do carry insurance against these risks, perform penetration tests from time to time, and design our business processes to attempt to mitigate the risk of such breaches. However, our efforts to mitigate these risks may be unsuccessful for security breaches not to occur. Moreover, the development and maintenance of these measures requires continuous monitoring as technologies change and efforts to overcome security measures evolve. We have experienced, and expect to continue to experience, cyber security threats and incidents, none of which has been material to us to date. However, a successful breach or attack could have a material negative impact on our operations and subject us to consequences such as direct costs associated with incident response.

**Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Item 2. PROPERTIES**

Our corporate headquarters and principal office is located in Boca Raton, Florida. Our corporate headquarters and principal office occupies approximately 8,926 square feet of leased space. The lease was last extended in January 2018 and will expire in September 2022. Our Israeli subsidiary entered into a two-year lease for office space in September 2018. Both of our leases contain escalating rent clauses. Our rental expense in 2018 was approximately $229,000. We believe that our current facilities are suitable and adequate to meet our current needs and that suitable additional space will be available as and when needed on acceptable terms. Our main manufacturing function is physically located at our third party manufacturer's facility in Oak Ridge, Tennessee.

**Item 3. LEGAL PROCEEDINGS**

We are party to certain legal proceedings in the ordinary course of business. We assess, in conjunction with our legal counsel, the need to record a liability for litigation and related contingencies.

**Item 4. MINE SAFETY DISCLOSURE**

Not applicable.



**PART II.**

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

**Common Stock Market Prices**

Our common stock trades on the Nasdaq Capital Market under the symbol "SRTS." We had a total of 44 stockholders of record as of March 8, 2019. The following table presents the range of high and low closing sales prices reported on the Nasdaq Capital Market.

| | 2018 | | | | 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| | Fourth Quarter | Third Quarter | Second Quarter | First Quarter | Fourth Quarter | Third Quarter | Second Quarter | First Quarter |
| Common stock price: | | | | | | | | |
| High | $ 8.72 | $ 8.38 | $ 7.71 | $ 5.97 | $ 6.00 | $ 6.01 | $ 4.65 | $ 5.24 |
| Low | 5.31 | 6.70 | 5.75 | 5.22 | 4.85 | 3.50 | 3.52 | 4.35 |
| Close | 7.41 | 8.38 | 7.26 | 5.84 | 5.16 | 4.98 | 4.52 | 4.39 |

**Dividends**

We have never declared or paid any dividend on our common stock. We anticipate that for the foreseeable future all earnings will be retained for use in our business and we do not expect to pay dividends to stockholders. Any future payment of cash dividends on our common stock will be dependent upon our financial condition, results of operations, current and anticipated cash requirements, plans for expansion, as well as other factors that our Board of Directors deems relevant. Additionally, certain contractual agreements and provisions of Delaware law impose restrictions on our ability to pay dividends. For example, our current revolving line of credit restricts our ability to pay dividends or make any distributions or payments or redeem, retire or purchase any capital stock without the prior written consent of the lender, provided that we may pay dividends solely in common stock without prior consent. Additionally, Section 170(a) of the Delaware General Corporation Law ("DGCL") only permits dividends to be paid out of two legally available sources: (1) out of surplus, or (2) if there is no surplus, out of net profits for the year in which the dividend is declared or the preceding year (so-called "nimble dividends"). However, dividends may not be declared out of net profits if "the capital of the corporation, computed in accordance with sections 154 and 244 of the DGCL, shall have been diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets." Contractual obligations and applicable law will restrict our ability to declare and pay dividends in the future.

**Unregistered Sales of Securities**

There were no unregistered sales of securities during the year ended December 31, 2018.

**Purchases of Equity Securities by the Registrant and Affiliated Purchasers**

None.

**Item 6. SELECTED FINANCIAL DATA**

Not applicable.

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

You should read the following management's discussion and analysis ("MD&A") in conjunction with the information set forth within the financial statements and related notes included in this Annual Report on Form 10-K. The following information should provide a better understanding of the major factors and trends that affect our earnings performance and financial condition, and how our performance during 2018 compares with the prior year. Throughout this section, Sensus Healthcare, Inc. is referred to as "Company," "we," "us," or "our."



**CAUTION CONCERNING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K, including this MD&A section, contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, among others, statements about our beliefs, plans, objectives, goals, expectations, estimates and intentions that are subject to significant risks and uncertainties and are subject to change based on various factors, many of which are beyond our control. The words "may," "could," "should," "would," "believe," "anticipate," "estimate," "expect," "intend," "plan," "target," "goal," and similar expressions are intended to identify forward-looking statements.

All forward-looking statements, by their nature, are subject to risks and uncertainties. Our actual future results may differ materially from those set forth in our forward-looking statements. Please see the Introductory Note and *Item 1A Risk Factors* of this Annual Report for a discussion of factors that could cause our actual results to differ materially from those in the forward-looking statements.

However, other factors besides those listed in *Item 1A Risk Factors* or discussed in this Annual Report also could adversely affect our results, and you should not consider any such list of factors to be a complete set of all potential risks or uncertainties. Any forward-looking statements made by us or on our behalf speak only as of the date they are made. We do not undertake to update any forward-looking statement, except as required by applicable law.

**Components of our results of operations**

We manage our business globally within one reportable segment, which is consistent with how our management reviews our business, prioritizes investment and resource allocation decisions and assesses operating performance.

***Revenue***

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" using the modified

retrospective method. The adoption of this standard did not result in a significant change to the Company's historical revenue recognition policies and there were no necessary adjustments required to retained earnings upon adoption.

Under ASC 606, a performance obligation is a promise within a contract to transfer a distinct good or service, or a series of distinct goods and services, to a customer. Revenue is recognized when performance obligations are satisfied and the customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for goods or services. Under the standard, a contract's transaction price is allocated to each distinct performance obligation. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identifies the contracts with a customer; (ii) identifies the performance obligations within the contract, including whether they are distinct and capable of being distinct in the context of the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when, or as, the Company satisfies each performance obligation.

The Company's revenue consists of sales of the Company's devices and services related to maintaining and repairing the devices. The agreement for the sale of the devices and the service contract are usually signed at the same time and in some instances a service contract is signed on a stand-alone basis. Revenue for service contracts is recognized over the service contract period on a straight-line basis. The Company determined that in practice no significant discount is given on the service contract when it is offered with the device purchase as compared to when it is sold on a stand-alone basis, by comparing the median selling price of the service contract as stand-alone and the median selling price of the service contract when sold together with the device. The service level provided is identical when the service contract is purchased stand-alone or together with the device. There is no termination provision in the service contract nor any penalties in practice for cancellation of the service contract. The service contract is not considered a performance obligation until it is paid, and it does not provide a material right for a significant discount when purchased with the device. The service portion of a sales contract or a stand-alone service contract is accounted for over the period of time of the service contract only when the customer exercises the option by paying for the service contract.



The Company operates in a highly-regulated environment in which state regulatory approval is sometimes required prior to the customer being able to use the product, primarily in the U.S. dermatology market. In these cases, where regulatory approval is pending, revenue is deferred until such time as regulatory approval is obtained.

***Cost of sales***

Since 2010, we have used a third party manufacturer for the production and manufacture of our main products, the SRT-100 product line, in accordance with our product specifications. Cost of sales consists primarily of direct material, direct labor, overhead, depreciation and amortization. A significant portion of our cost of sales consists of costs paid to our third party manufacturer.

***Gross profit***

We calculate gross profit as net revenue less cost of sales. Our gross profit has been and will continue to be affected by a variety of factors, including average selling price, manufacturing costs, production volumes, product reliability and the implementation over time of cost-reduction strategies. Our gross profit may fluctuate from quarter to quarter.

***Selling and marketing***

We focus on two primary markets - private dermatology practices and radiation oncologists in both private and hospital settings. We currently employ a multi-tier sales strategy in an attempt to optimize geographic coverage and focus on what we perceive to be our key markets. This multi-tier sales model uses a direct salesforce in the U.S. and international dealers and distributors.

***General and administrative***

General and administrative expense consists primarily of salaries, employee benefits, bonuses, and related costs for personnel who support our general operations such as executive management, finance, accounting and administrative functions, as well as legal and other professional fees, director and officer insurance and other public company expenses.

***Research and development***

Research and development costs relate to products under development by us and quality and regulatory costs and are expensed as incurred.

***Other income (expense)***

Other income (expense) primarily consists of interest earned on cash balances and investments less interest payments made pursuant to our secured credit facility with Silicon Valley Bank. Our interest expense will fluctuate in future periods to the extent we incur additional, or pay down, indebtedness.

***Income taxes***

Until December 31, 2015, we were organized as a limited liability corporation taxed as a pass-through entity and accordingly, we did not recognize a federal or state income tax provision. Beginning in 2016, as a result of our conversion to a Delaware corporation, we began recording a provision for income tax (benefit) expense, which consists of income taxes in jurisdictions in which we conduct business. We are taxed at the rates applicable within each jurisdiction in which we operate or generate revenue. The composite income tax rate, tax provisions, deferred tax assets and deferred tax liabilities vary according to the jurisdiction in which profits arise. Tax laws are complex and subject to different interpretations by management and the respective governmental taxing authorities, and require us to exercise judgment in determining our income tax provision, our deferred tax assets and liabilities and the valuation allowance recorded against our net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not that the future realization of all or some of the deferred tax assets will not be achieved.



On December 22, 2017, the United States enacted new federal tax reform legislation, resulting in significant changes from the prior tax law. The new tax law reduced the federal corporate income tax rate to 21% from 35%, effective January 1, 2018. Our federal income tax expense for periods beginning in 2018 was based on the new rate. The new tax law also permits immediate deduction of 100% of the costs of qualified property that have been incurred and the property placed in service during the period from September 27, 2017 to December 31, 2022. This provision will begin to phase out by 20% per year beginning January 1, 2023 and will be completely phased out as of January 1, 2027.

Our subsidiary in Israel is taxed on its taxable income. The current corporate tax rate in Israel is 23%.

***Inflation***

Inflation has not had a material impact on net sales, revenues or income from operations for our two most recent years as a result of historically low levels of inflation.

**Results of Operations**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| **Revenues** | $ 26,427,190 | $ 20,587,827 |
| **Cost of Sales** | 9,516,302 | 6,787,836 |
| **Gross Profit** | 16,910,888 | 13,799,991 |
| **Operating Expenses** | | |
| Selling and marketing | 8,531,622 | 8,305,315 |
| General and administrative | 4,124,214 | 3,721,627 |
| Research and development | 6,260,406 | 5,490,489 |
| **Total Operating Expenses** | 18,916,242 | 17,517,431 |
| **Loss From Operations** | (2,005,354) | (3,717,440) |
| **Other Income (Expense)** | | |
| Interest income | 139,278 | 75,807 |
| Interest expense | (156,685) | (68,881) |
| **Other Income (Expense), net** | (17,407) | 6,926 |
| **Net Loss** | $ (2,022,761) | $ (3,710,514) |

**Year ended December 31, 2018 compared to the year ended December 31, 2017**

***Total revenue.*** Total revenue was $26,427,190 for the year ended December 31, 2018 compared to $20,587,827 for the year ended December 31, 2017, an increase of $5,839,363, or 28.4%. The growth in revenue was attributable to an increase in the volume of systems sold as well as a higher percentage of sales of the higher-priced SRT-100 Vision product in the current year.

***Total cost of sales.*** Cost of sales was $9,516,302 for the year ended December 31, 2018 compared to $6,787,836 for the year ended December 31, 2017, an increase of $2,728,466, or 40.2%. The increase in cost was due to a greater number of systems sold during the year ended December 31, 2018 compared to the corresponding period in 2017.

***Gross profit.*** Gross profit was $16,910,888 for the year ended December 31, 2018 compared to $13,799,991 for the year ended December 31, 2017, an increase of $3,110,897 or 22.5%, for the reasons discussed above. Our overall gross profit margin was 64.0% in the year ended December 31, 2018 compared to 67.0% in the corresponding period in 2017, mainly due to the mix of products sold during 2018.



***Selling and marketing.*** Selling and marketing expense was $8,531,622 for the year ended December 31, 2018 compared to $8,305,315 for the year ended December 31, 2017, an increase of $226,307 or 2.7%. The increase was primarily attributable to an increase in commission expense directly related to the increase in sales offset by a reduction in marketing activities during 2018.

***General and administrative.*** General and administrative expense was $4,124,214 for the year ended December 31, 2018 compared to $3,721,627 for the year ended December 31, 2017, an increase of $402,587, or 10.8%. The net increase was due primarily to stock compensation expense of $444,000 from the grant of fully vested shares to directors.

***Research and development.*** Research and development expense was $6,260,406 for the year ended December 31, 2018 compared to $5,490,489 for the year ended December 31, 2017, an increase of $769,917 or 14.0%. The increase in research and development spending was attributable to the acceleration of research projects in 2018.

***Other income (expense).*** We incur interest expense in connection with our secured credit facility with Silicon Valley Bank and interest income from our investment in held-to-maturity securities and cash equivalents. Other income, net increased in 2018 due to interest on the net proceeds received from the share offering in September 2018.

**Financial Condition**

Our cash, cash equivalent and investment balance increased to $15,376,446 at December 31, 2018 from $11,190,103 at December 31, 2017, primarily as a result of the net public offering proceeds from our shelf take down in September 2018 of approximately $15.8 million, partially offset by the cash used in operations during 2018.

Borrowings under the revolving line of credit were $0 as of December 31, 2018, compared to $2,214,970 at December 31, 2017. Outstanding borrowings under the line of credit were repaid from the proceeds of the shelf takedown.

**Liquidity and Capital Resources**

***Overview***

In general terms, liquidity is a measurement of our ability to meet our cash needs. For the years ended December 31, 2018 and 2017, a significant source of funding has been from cash flows from financing activities, including our public offering in 2018, as well as from borrowings under our revolving line of credit. We believe that proceeds from our public offerings, our borrowing capacity and our access to capital resources are sufficient to meet our anticipated operating capital and funding requirements for the foreseeable future. Our liquidity position and capital requirements may be impacted by a number of factors, including the following:

- our ability to generate and increase revenue;
- fluctuations in gross margins, operating expenses and net results; and
- fluctuations in working capital.

Our primary short-term capital needs, which are subject to change, include expenditures related to:

- expansion of our sales and marketing activities; and
- expansion of our research and development activities.

We regularly evaluate our cash requirements for current operations, commitments, capital requirements and business development transactions, and we may elect to raise additional funds for these purposes in the future.

***Cash flows***

The following table provides a summary of our cash flows for the periods indicated:

| | For the Years Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| **Net Cash Provided by (Used In):** | | |
| Operating Activities | $ (8,517,760) | $ (3,056,606) |
| Investing Activities | (2,688,360) | 6,173,913 |
| Financing Activities | 13,604,908 | 1,925,684 |
| **Increase In Cash and Cash Equivalents** | $ 2,398,788 | $ 5,042,991 |

***Cash flows from operating activities***

Net cash used in operating activities was $8,517,760 for the year ended December 31, 2018, consisting of a net loss of $2,022,761 and an increase in net operating assets of $8,244,406, partially offset by non-cash charges of $1,749,406. The increase in net operating assets was primarily due to the increase in sales and other longer payment terms on certain sales, resulting in an increase in accounts receivable, an increase in prepaid and other current assets and an increase in account payable and accrued expenses. Non-cash charges consisted primarily of stock compensation expense and depreciation and amortization. Net cash used in operating activities was $3,056,606 for the year ended December 31, 2017, consisting of a net loss of $3,710,514 and an increase in net operating assets of $568,857, offset by non-cash charges of $1,222,765.

***Cash flows from investing activities***

Net cash used in investing activities was $2,688,360 due the purchase of debt securities held-to-maturity of $2,892,190 and $900,805 for acquisition of property and equipment offset by matured investments of $1,104,635 during the year ended December 31, 2018. Net cash provided in investing activities totaled $6,173,913 for the year ended December 31, 2017, which consisted of matured investments of $6,461,507 less $287,594 for acquisition of property and equipment.

***Cash flows from financing activities***

Net cash provided by financing activities was $13,604,908 during the year ended December 31, 2018, mostly from the gross proceeds of $17,249,995 from the offering of common stock and $90,867 from exercise of warrants, partially offset by $2,214,970 repayment of our revolving credit facility, offering costs of $1,402,336 and $118,648 in withholding tax on stock compensation. Net cash provided by financing activities was $1,925,684 during the year ended December 31, 2017 of which $2,214,970 was from borrowing under our line of credit, partially offset by $289,286 on withholding taxes paid on stock compensation.

***Indebtedness***

Please see Note 4 to the financial statements.

**Contractual Obligations and Commitments**

In July 2016, we renewed our lease with an unrelated third party for its headquarters office. The renewal was effective September 1, 2016 and expanded the office space being occupied. The lease expires in September 2022 and lease payments increase by 3% annually. In February 2017 and January 2018, we signed amendments to further expand our leased office space. Our wholly owned Israeli subsidiary also entered into a two-year lease for office space in September 2018. Future minimum lease payments as of December 31, 2018 are as follows:

| Year | Minimum Lease Payment |
|---|---|
| 2019 | $ 249,000 |
| 2020 | 245,000 |
| 2021 | 231,000 |
| 2022 | 177,000 |
| **Total** | $ 902,000 |



**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and do not currently have, any off-balance sheet arrangements.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S., or GAAP. We have identified certain accounting policies as critical to understanding our financial condition and results of our operations. For a detailed discussion on the application of these and other accounting policies, see the notes to our financial statements included in this Annual Report on Form 10-K.

**JOBS Act**

We qualify as an "emerging growth company" pursuant to the provisions of the JOBS Act. For as long as we are an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are 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(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, reduced disclosure obligations relating to the presentation of financial statements in Management's Discussion and Analysis of Financial Condition and Results of Operations, exemptions from the requirements of holding advisory "say-on-pay" votes on executive compensation and stockholder advisory votes on golden parachute compensation. We have availed ourselves of the reduced reporting obligations and executive compensation disclosure in this Annual Report on Form 10-K, and expect to continue to avail ourselves of the reduced reporting obligations available to emerging growth companies in future filings.

In addition, an emerging growth company can delay its adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period, and as a result, we plan to comply with any new or revised accounting standards on the relevant dates on which non-emerging growth companies must adopt such standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Not applicable.



**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**FINANCIAL STATEMENTS OF SENSUS HEALTHCARE, INC.**
**CONTENTS**





**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders and Board of Directors of
Sensus Healthcare, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Sensus Healthcare, Inc. (the "Company") as of December 31, 2018 and 2017, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

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

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

Our 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/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2012.

Fort Lauderdale, FL
March 15, 2019



**SENSUS HEALTHCARE, INC.**
**BALANCE SHEETS**

| | As of December 31, | |
|---|---|---|
| | **2018** | **2017** |
| **Assets** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 12,484,256 | $ 10,085,468 |
| Accounts receivable, net | 13,145,934 | 4,958,255 |
| Inventories | 1,628,817 | 1,171,383 |
| Investment in debt securities | 2,892,190 | 1,104,635 |
| Prepaid and other current assets | 1,750,994 | 566,972 |
| **Total Current Assets** | 31,902,191 | 17,886,713 |
| **Property and Equipment, Net** | 891,029 | 394,078 |
| **Patent Rights, Net** | 433,737 | 530,123 |
| **Deposits** | 24,272 | 24,272 |
| **Total Assets** | $ 33,251,229 | $ 18,835,186 |
| **Liabilities and Stockholders' Equity** | | |
| **Current Liabilities** | | |

| | | |
|---|---|---|
| Accounts payable and accrued expenses | $ 5,166,239 | $ 4,067,894 |
| Product warranties | 136,217 | 146,722 |
| Deferred revenue, current portion | 722,025 | 652,242 |
| **Total Current Liabilities** | 6,024,481 | 4,866,858 |
| **Revolving Credit Facility** | — | 2,214,970 |
| **Deferred Revenue, Net of Current Portion** | 766,732 | 73,083 |
| **Total Liabilities** | 6,791,213 | 7,154,911 |
| **Commitments and Contingencies** | | |
| **Stockholders' Equity** | | |
| Preferred stock, 5,000,000 shares authorized and none issued and outstanding | — | — |
| Common stock, $0.01 par value – 50,000,000 authorized; 16,145,915 issued and 16,112,461 outstanding at December 31, 2018; 13,522,168 issued and 13,488,714 outstanding at December 31, 2017 | 161,459 | 135,221 |
| Additional paid-in capital | 39,957,905 | 23,181,641 |
| Treasury stock, 33,454 shares at cost, at December 31, 2018 and 2017. | (133,816) | (133,816) |
| Accumulated deficit | (13,525,532) | (11,502,771) |
| **Total Stockholders' Equity** | 26,460,016 | 11,680,275 |
| **Total Liabilities and Stockholders' Equity** | $ 33,251,229 | $ 18,835,186 |

See accompanying notes to the consolidated financial statements.



**SENSUS HEALTHCARE, INC.**
**STATEMENTS OF OPERATIONS**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| **Revenues** | $ 26,427,190 | $ 20,587,827 |
| **Cost of Sales** | 9,516,302 | 6,787,836 |
| **Gross Profit** | 16,910,888 | 13,799,991 |
| **Operating Expenses** | | |
| Selling and marketing | 8,531,622 | 8,305,315 |
| General and administrative | 4,124,214 | 3,721,627 |
| Research and development | 6,260,406 | 5,490,489 |
| **Total Operating Expenses** | 18,916,242 | 17,517,431 |
| **Loss From Operations** | (2,005,354) | (3,717,440) |
| **Other Income (Expense)** | | |
| Interest income | 139,278 | 75,807 |
| Interest expense | (156,685) | (68,881) |
| **Other Income (Expense), net** | (17,407) | 6,926 |
| **Net Loss** | $ (2,022,761) | $ (3,710,514) |
| **Net Loss per share – basic and diluted** | $ (0.14) | $ (0.28) |
| **Weighted average number of shares used in computing net loss per share – basic and diluted** | 14,115,757 | 13,236,519 |

See accompanying notes to the consolidated financial statements.



**SENSUS HEALTHCARE, INC.**
**STATEMENTS OF STOCKHOLDERS' EQUITY**
**FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017**

| | Common Stock | | Additional Paid-In | Treasury Stock | | Accumulated | |
|---|---|---|---|---|---|---|---|
| | **Shares** | **Amount** | **Capital** | **Shares** | **Amount** | **Deficit** | **Total** |
| **December 31, 2016** | 13,546,171 | $ 135,461 | $ 22,930,975 | — | $ — | $ (7,792,257) | $ 15,274,179 |
| Stock based compensation | 5,000 | 50 | 405,846 | — | — | — | 405,896 |
| Surrender of shares for tax withholding on stock compensation | (29,003) | (290) | (155,180) | (33,454) | (133,816) | — | (289,286) |
| Net loss | — | — | — | — | — | (3,710,514) | (3,710,514) |
| **December 31, 2017** | 13,522,168 | $ 135,221 | $ 23,181,641 | (33,454) | $ (133,816) | $ (11,502,771) | $ 11,680,275 |
| Issuance of common stock for cash, net of offering cost | 2,563,764 | 25,638 | 15,822,021 | — | — | — | 15,847,659 |
| Stock based compensation | 50,000 | 500 | 982,124 | — | — | — | 982,624 |
| Surrender of shares for tax withholding on stock compensation | (19,305) | (193) | (118,455) | — | — | — | (118,648) |
| Exercise of warrants and options | 29,288 | 293 | 90,574 | — | — | — | 90,867 |
| Net loss | — | — | — | — | — | (2,022,761) | (2,022,761) |
| **December 31, 2018** | 16,145,915 | $ 161,459 | $ 39,957,905 | (33,454) | $ (133,816) | $ (13,525,532) | $ 26,460,016 |

See accompanying notes to the consolidated financial statements.



**SENSUS HEALTHCARE, INC.**
**STATEMENTS OF CASH FLOWS**

| | For the Years Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| **Cash Flows From Operating Activities** | | |
| Net loss | $ (2,022,761) | $ (3,710,514) |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities: | | |
| Bad debt expense (recoveries) | (13,280) | 191,391 |
| Depreciation and amortization | 658,255 | 387,917 |
| Provision for product warranties | 121,807 | 237,561 |
| Stock based compensation | 982,624 | 405,896 |
| Decrease (increase) in: | | |
| Accounts receivable | (8,174,399) | (2,051,011) |
| Inventories | (661,419) | 118,925 |
| Prepaid and other current assets | (1,184,023) | 333,751 |
| Increase (decrease) in: | | |
| Accounts payable and accrued expenses | 1,098,344 | 1,305,522 |
| Deferred revenue | 763,432 | (144,724) |
| Product warranties | (132,311) | (131,320) |
| **Total Adjustments** | (6,540,970) | 653,907 |
| **Net Cash Used In Operating Activities** | (8,563,731) | (3,056,606) |
| **Cash Flows from Investing Activities** | | |
| Acquisition of property and equipment | $ (854,834) | $ (287,594) |
| Investment in debt securities - held to maturity | (2,892,190) | — |
| Investments matured | 1,104,635 | 6,461,507 |
| **Net Cash Provided By (Used In) Investing Activities** | (2,642,389) | 6,173,913 |
| **Cash Flows from Financing Activities** | | |
| Offering of common stock | 17,249,995 | — |
| Revolving credit facility, net | (2,214,970) | 2,214,970 |
| Offering costs | (1,402,336) | — |
| Withholding taxes on stock compensation | (118,648) | (289,286) |
| Exercise of warrants | 90,867 | — |
| **Net Cash Provided By Financing Activities** | 13,604,908 | 1,925,684 |
| **Net Increase in Cash and Cash Equivalents** | 2,398,788 | 5,042,991 |
| **Cash and Cash Equivalents – Beginning** | 10,085,468 | 5,042,477 |
| **Cash and Cash Equivalents – Ending** | $ 12,484,256 | $ 10,085,468 |
| **Supplemental Disclosure of Cash Flow Information** | | |
| Interest Paid | $ 156,685 | $ 43,316 |
| **Non Cash Investing and Financing Activities** | | |
| Transfer of inventory to property and equipment | $ 203,987 | $ 35,393 |

See accompanying notes to the consolidated financial statements.



**SENSUS HEALTHCARE, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**

## NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### *DESCRIPTION OF THE BUSINESS*

Sensus Healthcare, Inc. (the "Company") is a manufacturer of superficial radiation therapy devices and has established a distribution and marketing network to sell the devices to healthcare providers globally. The Company was organized on May 7, 2010 as a limited liability corporation. On January 1, 2016, the Company completed a corporate conversion pursuant to which Sensus Healthcare, Inc. succeeded to the business of Sensus Healthcare, LLC. In February 2018, the Company opened a subsidiary in Israel. The Company operates as one segment from its corporate headquarters located in Boca Raton, Florida.

### *PRINCIPLES OF CONSOLIDATION*

The accompanying condensed consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiary in Israel. All inter-company balances and transactions have been eliminated.

### *USE OF ESTIMATES*

The preparation of 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 assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates to which it is reasonably possible that a change could occur in the near term include, revenue recognition, inventory reserves, receivable allowances, recoverability of long lived assets and estimation of the Company's product warranties. Actual results could differ from those estimates.

### *REVENUE RECOGNITION*

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" using the modified retrospective method for all contracts as of the date of adoption. The adoption of this standard did not result in a significant change to the Company's historical revenue recognition policies and there were no necessary adjustments required to retained earnings upon adoption.

Under ASC 606, a performance obligation is a promise within a contract to transfer a distinct good or service, or a series of distinct goods and services, to a customer. Revenue is recognized when performance obligations are satisfied and the customer obtains control of promised goods or services, which is generally upon shipment of the goods and performance of the service. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for goods or services. Under the standard, a contract's transaction price is allocated to each distinct performance obligation. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identifies the contracts with a customer; (ii) identifies the performance obligations within the contract, including whether they are distinct and capable of being distinct in the context of the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when, or as, the Company satisfies each performance obligation.

The Company's revenue consists of sales of the Company's devices and services related to maintaining and repairing the devices. The agreement for the sale of the devices and the service contract are usually signed at the same time and in some instances a service contract is signed on a stand-alone basis. Revenue for service contracts is recognized over the service contract period on a straight-line basis. The Company determined that in practice no significant discount is given on the

service contract when it is offered with the device purchase as compared to when it is sold on a stand-alone basis, by comparing the median selling price of the service contract as stand-alone and the median selling price of the service contract when sold together with the device. The service level provided is identical when the service contract is purchased stand-alone or together with the device. There is no termination provision in the service contract nor any penalties in practice for cancellation of the service contract. The service contract is not considered a performance obligation until it is paid, and it does not provide a material right for a significant discount when purchased with the device. The service portion of a sales contract or a stand-alone service contract is accounted for over the period of time of the service contract only when the customer exercises the option by paying for the service contract.



Disaggregated revenue for the year ended December 31, 2018 and 2017 was as follows:

| | For the Years Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Product Revenue | $ 24,651,212 | $ 19,003,723 |
| Service Revenue | 1,775,978 | 1,584,104 |
| **Total Revenue** | $ 26,427,190 | $ 20,587,827 |

The Company operates in a highly-regulated environment in which state regulatory approval is sometimes required prior to the customer being able to use the product, primarily in the U.S. dermatology market. In these cases, where regulatory approval is pending, revenue is deferred until such time as regulatory approval is obtained.

Deferred revenue as of December 31, 2018 was as follows:

| | **Service** | **Product** | **Total Deferred Revenue** |
|---|---|---|---|
| Balance, beginning of period | $ 643,325 | $ 82,000 | $ 725,325 |
| Revenue recognized | (1,344,588) | (49,000) | (1,393,588) |
| Amounts invoiced | 2,157,020 | — | 2,157,020 |
| **Balance, end of period** | $ 1,455,757 | $ 33,000 | $ 1,488,757 |

Deferred revenue increased due to new service contracts during the year ended December 31, 2018.

The Company does not disclose information about remaining performance obligations of deposits for products that have original expected durations of one year or less. Estimated service revenue to be recognized in the future related to the performance obligations that are unsatisfied (or partially unsatisfied) as of December 31, 2018 is as follows:

| **Year** | **Service Revenue** |
|---|---|
| 2019 | $ 674,026 |
| 2020 | 441,270 |
| 2021 | 325,893 |
| 2022 | 14,568 |
| **Total** | $ 1,455,757 |

The Company provides warranties, generally for one year, in conjunction with the sale of its product. These warranties entitle the customer to repair, replacement, or modification of the defective product subject to the terms of the respective warranty. The Company records an estimate of future warranty claims at the time the Company recognizes revenue from the sale of the product based upon management's estimate of the future claims rate.

Shipping and handling costs are expensed as incurred and are included in cost of sales.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents, accounts receivable and investments in debt securities.



***Segment and Geographical Information***

The Company's revenue is generated primarily from customers in the United States, which represented approximately 96% and 97% of revenue for the years ended December 31, 2018 and 2017, respectively. A single customer in the U.S. accounted for approximately 71% and 59% of revenue for the years ended December 31, 2018 and 2017, respectively, and 87% of the accounts receivable as of December 31, 2018 and 2017.

***Fair Value of Financial Instruments***

Carrying amounts of cash equivalents, accounts receivable, accounts payable and revolving credit facility approximate fair value due to their relative short maturities.

***Cash and Cash Equivalents***

The Company maintains its cash and cash equivalents with financial institutions which balances exceed the federally insured limits. Federally insured limits are $250,000 for deposits. As of December 31, 2018 and 2017, the Company had approximately $11,726,000 and $9,952,000, respectively in excess of federally insured limits.

For purposes of the statement of cash flows, the Company considers all highly liquid financial instruments with a maturity of three months or less when purchased to be a cash equivalent.

***Investments***

Short-term investments consist of investments which the Company expects to convert into cash within one year and long-term investments after one year. The Company classifies its investments in debt securities at the time of purchase as held-to-maturity and re-evaluates such classification on a quarterly basis. Held-to-maturity investments consist of securities that the Company has the intent and ability to retain until maturity. These securities are carried at amortized cost plus accrued interest and consist of the following:

| | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Fair Value |
|---|---|---|---|---|
| **Short Term:** | | | | |
| Corporate bonds | $ 602,599 | $ — | $ 256 | $ 602,343 |
| United States Treasury bonds | 502,036 | — | 332 | 501,704 |
| **Total Short Term:** | 1,104,635 | — | 588 | 1,104,047 |
| | | | | |
| **Total Investments December 31, 2017** | $ 1,104,635 | $ — | $ 588 | $ 1,104,047 |
| **Short Term:** | | | | |
| Corporate bonds | $ 2,892,190 | $ — | $ 623 | $ 2,891,567 |
| **Total Short Term:** | 2,892,190 | — | 623 | 2,891,567 |
| | | | | |
| **Total Investments December 31, 2018** | $ 2,892,190 | $ — | $ 623 | $ 2,891,567 |

***Accounts Receivable***

The Company does business and extends credit based on an evaluation of each customer's financial condition, generally without requiring collateral. Exposure to losses on receivables is expected to vary by customer due to the financial condition of each customer. The Company monitors exposure to credit losses and maintains allowances for anticipated losses considered necessary under the circumstances. The allowance for doubtful accounts was approximately $0 and $16,000 as of December 31, 2018 and 2017, respectively. Bad debt recoveries and expense for the years ended December 31, 2018 and 2017 was approximately $13,000 in recoveries and $191,000 in expense, respectively.



***Inventories***

Inventories consist of finished product and components and are stated at the lower of cost and net realizable value, determined using the first-in-first-out method.

***Property and Equipment***

Property and equipment are stated at cost. Depreciation on property and equipment is calculated on the straight-line basis over the estimated useful life of each asset. Maintenance and repairs are expensed as incurred; expenditures that enhance the value of property or extend their useful lives are capitalized. When assets are sold or returned, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in income.

Inventory units designated for customer demonstrations, as part of the sales process, are reclassified to property and equipment and the depreciation is recorded to selling and marketing expense. The inventory used for demonstrations that was reclassified to property and equipment for the years ended December 31, 2018 and 2017 was approximately $158,000 and $35,000, respectively.

***Intangible Assets***

Intangible assets are comprised of the Company's patent rights and are amortized over the patents' estimated useful life of approximately 13 years. As of December 31, 2018, the remaining useful life was 54 months.

***Long-Lived Assets***

The Company evaluates its long-lived assets, including intangible assets, for possible impairment whenever circumstances indicate that the carrying amount of the asset, or related group of assets, may not be recoverable from estimated future cash flows in accordance with accounting guidance. If circumstances suggest the recorded amounts cannot be recovered, based upon estimated future undiscounted cash flows, the carrying values of such assets are reduced to fair value. No impairment charges were recorded for long-lived assets for the years ended December 31, 2018 and 2017.

***Research and Development***

Research and development costs related to products under development by the Company and quality and regulatory costs and are expensed as incurred.

***Earnings Per Share***

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding for the period using the treasury stock method for options and warrants. The diluted net income per share is computed by giving effect to all potential dilutive common share equivalents outstanding for the period. In periods when the Company has incurred a net loss, options and warrants to purchase common shares are considered common share equivalents but have been excluded from the calculation of diluted net loss per share as their effect is antidilutive. Shares excluded were computed under the treasury stock method as follows:

| | For the Years Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Stock options | 31,694 | — |
| Restricted shares | 17,365 | — |
| Warrants | — | 4,076 |

***Equity-Based Compensation***

Pursuant to relevant accounting guidance related to accounting for equity-based compensation, the Company is required to recognize all share-based payments to non-employees and employees in the financial statements based on fair values on the grant date. The Company has accounted for issuance of shares, options, and warrants in accordance with the guidance, which requires the recognition of expense, based on grant-date fair values, over the service period, generally periods over which the shares, options and warrants vest.



***Advertising Costs***

Advertising and promotion expenses are charged to expense as incurred. Advertising and promotion expense included in selling and marketing expense in the

accompanying statements of operations amounted to approximately $1,462,000 and $1,684,000 for the years ended December 31, 2018 and 2017, respectively.

***Operating Leases***

Rent expense for operating leases which contain escalating rental clauses is recorded on a straight-line basis over the lease term.

***Recently issued and adopted accounting standards***

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 eliminated transaction- and industry-specific revenue recognition guidance under current GAAP and replaced it with a principle based approach for determining revenue recognition. ASU 2014-09 requires that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. In April 2016, the FASB also issued ASU 2016-10, Identifying Performance Obligations and Licensing, implementation guidance on principal versus agent, identifying performance obligations, and licensing. ASU 2016-10 is effective for reporting periods beginning after December 15, 2017. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company adopted the new revenue recognition standard in the first quarter of 2018 using the full retrospective method. The Company's revenues were not materially impacted as a result of applying ASC 606 for the year ended December 31, 2018, and there have not been significant changes to the Company's business processes, systems, or internal controls as a result of implementing the standard.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." The guidance in ASU 2016-02 supersedes the lease recognition requirements in ASC Topic 840, Leases (FAS 13). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 1, 2018, including interim periods within those fiscal years, with early adoption 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 comparative period presented in the financial statements. Early adoption of the amendments in the update is permitted. We will adopt the updated accounting guidance in the first quarter of 2019, but prior periods will not be adjusted. The Company does not expect this standard will have a material impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718) – Scope of Modification Accounting. The amendments included in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this update will be applied prospectively to an award modified on or after the adoption date. The amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The Company adopted this standard in the first quarter of 2018 and it did not have a material impact on its financial statements.



**Note 2 — Property and Equipment**

| | As of December 31, | | Estimated Useful |
|---|---|---|---|
| | 2018 | 2017 | Lives |
| Operations and rental equipment | $ 852,273 | $ 542,639 | 3 years |
| Tradeshow and demo equipment | 784,244 | 271,275 | 3 years |
| Computer equipment | 112,521 | 94,298 | 3 years |
| | 1,749,038 | 908,212 | |
| Less accumulated depreciation | (858,009) | (514,134) | |
| **Property and Equipment, Net** | $ 891,029 | $ 394,078 | |

Depreciation expense was approximately $562,000 and $291,000 for the years ended December 31, 2018 and 2017, respectively. Accumulated depreciation on asset disposals was approximately $218,000 for the year ended December 31, 2018.

**Note 3 — Patent Rights**

| | As of December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Gross carrying amount | $ 1,253,018 | $ 1,253,018 |
| Less accumulated amortization | (819,281) | (722,895) |
| **Patent Rights, Net** | $ 433,737 | $ 530,123 |

Amortization expense was approximately $96,000 for the years ended December 31, 2018 and 2017. As of December 31, 2018, future remaining amortization expense is as follows:

| For the Year Ending December 31, | |
|---|---|
| 2019 | $ 96,386 |
| 2020 | 96,386 |
| 2021 | 96,386 |
| 2022 | 96,386 |
| 2023 | 48,193 |
| **Total** | $ 433,737 |

**Note 4 — Revolving Credit Facility**

On March 12, 2013, the Company entered into a two-year $3 million revolving credit facility. The credit facility was amended and extended effective March 12, 2015 through May 12, 2017. The maximum borrowing was reduced to $1,500,000 and was limited by the Company's eligible borrowing base of 80% of eligible accounts receivable. On September 21, 2016, a second amendment to the credit facility extended the facility through September 21, 2017, increased the maximum borrowing to $2,000,000 and expanded the eligible accounts receivables to include certain international receivables. The Company was not in compliance in April and May 2017 with one of its financial covenants. On June 27, 2017, the covenant defaults were waived and the agreement was amended to modify the financial covenants effective June 2017. An amendment signed on September 15, 2017 extended the maturity date of the credit line through November 19, 2017. On October 31, 2017, the Company amended its revolving credit facility to extend the maturity to October 31, 2019 and to amend the financial covenants. The availability under the amended facility will equal the lesser of the $5 million commitment amount or the borrowing base plus the $2.5 million non-formula sublimit. The borrowing base consists of 80% of eligible accounts receivable, as defined in the agreement.

Interest, at Prime plus 0.75% (6.25% at December 31, 2018) and Prime plus 1.50% on non-formula borrowings (7.00% at December 31, 2018), is payable monthly, and the outstanding principal and interest are due on the maturity date. The facility is secured by all of the Company's assets and limits the amount of additional indebtedness, restricts the sale, disposition or transfer of assets of the Company and requires the maintenance of a certain monthly adjusted quick ratio restrictive covenant, as defined in the agreement. The Company was in compliance with its financial covenants as of December 31, 2018 and December 31, 2017. There were no borrowings outstanding under the revolving credit facility at December 31, 2018 and approximately $2,215,000 was outstanding at December 31, 2017. The Company pays commitment fees of 0.25% per annum on the average unused portion of the line of credit.

**NOTE 5 — PRODUCT WARRANTIES**

Changes in product warranty liability were as follows for the year ended December 31, 2018:

| | | |
|---|---|---|
| Balance, beginning of period | $ | 146,722 |
| Warranties accrued during the period | | 121,807 |
| Payments on warranty claims | | (132,312) |
| **Balance, end of period** | $ | 136,217 |

**NOTE 6 — COMMITMENT AND CONTINGENCIES**

***OPERATING LEASE AGREEMENTS***

In July 2016, the Company renewed its lease with an unrelated third party for its headquarters office. The renewal was effective September 1, 2016 and expanded the office space being occupied. The lease expires in September 2022 and lease payments increase by 3% annually. In February 2017 and January 2018, the Company signed amendments to expand further the leased office space. The Company's Israeli subsidiary entered into a two year lease for office space starting in September 2018. Future minimum lease payments as of December 31, 2018 are as follows:

| Year | | Minimum Lease Payment |
|---|---|---|
| 2019 | $ | 249,000 |
| 2020 | | 245,000 |
| 2021 | | 231,000 |
| 2022 | | 177,000 |
| **Total** | $ | 902,000 |

Rental expense for year ended December 31, 2018 and 2017 was approximately $229,000 and $178,000, respectively.

***MANUFACTURING AGREEMENT***

In July 2010, the Company entered into a three-year contract manufacturing agreement with an unrelated third party for the production and manufacture of the Company's main product in accordance with the Company's product specifications. The agreement renews for successive years unless either party notifies the other party in writing, at least 60 days prior to the anniversary date of this agreement that it will not renew the agreement. The Company or the manufacturer has the option to terminate the agreement with 90 days written notice.

Purchases from this manufacturer totaled approximately $4,185,000 and $3,838,000 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, approximately $1,041,000 and $829,000, respectively, was due to this manufacturer, which is presented in accounts payable and accrued expenses in the accompanying balance sheets.



***LEGAL CONTINGENCIES***

The Company is party to certain legal proceedings in the ordinary course of business. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and related contingencies.

In November 2015, the Company learned that the Department of Justice (the "Department") had commenced an investigation of the billing to Medicare by a physician who had treated patients with the Company's SRT-100. The Company received a Civil Investigative Demand from the Department seeking documents and written responses in connection with that investigation. The Company has fully cooperated with the investigation. The Department has advised the Company that it was considering expanding the investigation to determine whether the Company had any involvement in the physician's use of certain reimbursement codes. The Company disputes that it has engaged in any wrongdoing with respect to such reimbursement claims; among other things, the Company does not submit claims for reimbursement or provide coding or billing advice to physicians. To the Company's knowledge, the Department has made no determination as to whether the Company engaged in any wrongdoing, or whether to pursue any legal action against the Company. Should the Department decide to pursue legal action, the Company believes it has strong and meritorious defenses and will vigorously defend itself. At this time, the Company is unable to estimate the cost associated with this matter.

**NOTE 7 — EMPLOYEE BENEFIT PLANS**

We sponsor a 401(k) defined contribution retirement plan that allows eligible employees to contribute a portion of their compensation through payroll deductions in accordance with specified plan guidelines. We make contributions to the plans that include matching a percentage of the employees' contributions up to certain limits. Expenses related to this plan totaled approximately $107,000 and $95,000 for the years ended December 31, 2018 and 2017, respectively.

**NOTE 8 — STOCKHOLDERS'EQUITY**

The Company has authorized 50,000,000 shares of common stock, of which 16,145,915 were issued and 16,112,461 outstanding at December 31, 2018; 13,522,168 shares were issued and 13,488,714 outstanding as of December 31, 2017, respectively.

***STOCK ISSUANCES***

On September 17, 2018, the Company completed a public offering of 2,205,882 shares of its common stock, par value $0.01 per share, at a public offering price of $6.80 per share. On September 21, 2018 the Company issued an additional 330,882 shares of its common stock pursuant to the exercise in full of the underwriters' option received in connection with the public offering of its common stock. After giving effect to the full exercise of the option, Sensus sold an aggregate of 2,536,764 shares of its common stock at a price of $6.80 per share with total gross proceeds of approximately $17.25 million, and net proceeds of $15.85 million after deducting underwriting discounts and commissions and other offering expenses.

***WARRANTS***

In April 2013, the closing date of the Company's second common offering, the Company's placement agent received investor rights to five-year warrants to purchase 86,376 common shares of the Company at an exercise price of $4.55 per unit, which was equal to 110% of the offering price. During the first quarter of 2018, 73,309 of the warrants were exercised, and 13,067 warrants expired.

In June 2016, from the Company's IPO, the investors received three-year warrants to purchase 2,300,000 shares of common stock at an exercise price of $6.75 per share; the warrants are exercisable through June 8, 2019. Following the first anniversary of the date of issuance, if certain conditions are met, the Company may redeem any and all of the outstanding warrants at a price equal to $0.01 per warrant.



In addition, the underwriter's representatives for the IPO received four-year warrants to purchase up to 138,000 units, consisting of one share of common stock and one warrant to purchase one share of common stock. The warrants for the units are exercisable between June 2, 2017 and June 2, 2021 at an exercise price of $6.75 per unit.

The following table summarizes the Company's warrant activity:

| | Number of Warrants | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (In Years) |
|---|---|---|---|
| **Outstanding – December 31, 2017** | 2,524,376 | $ 6.67 | 1.50 |
| Granted | — | — | — |
| Exercised | (73,309) | 4.55 | — |
| Expired | (13,067) | 4.55 | — |
| **Outstanding – December 31, 2018** | 2,438,000 | $ 6.75 | 0.55 |
| **Exercisable – December 31, 2018** | 2,438,000 | $ 6.75 | 0.55 |

The intrinsic value of the common stock warrants was approximately $1,609,000 as of December 31, 2018, and $19,000 as of December 31, 2017.

***2016 AND 2017 EQUITY INCENTIVE PLANS***

The Company has limited the aggregate number of shares of common stock to be awarded under the 2016 Equity Incentive Plan to 397,473 shares and no more than 397,473 shares of common stock in the aggregate may be granted in connection with incentive stock options. The Company has limited the aggregate number of shares of common stock to be awarded under the 2017 Equity Incentive Plan to 500,000 shares and no more than 500,000 shares of common stock in the aggregate may be granted in connection with incentive stock options. In addition, unless the Compensation Committee specifically determines otherwise, the maximum number of shares available under the 2016 and 2017 Plans and the awards granted under those plans will be subject to appropriate adjustment in the case of any stock dividends, stock splits, recapitalizations, reorganizations, mergers, consolidations, exchanges or other changes in capitalization affecting our common stock.

On June 2, 2016, 307,666 shares of restricted stock were issued to employees and were recorded at the fair value of $5.25 as per the initial offering price. In addition, on January 20, 2017, 10,000 shares of restricted stock were issued to one employee and were recorded at the fair value of $4.99 per share and on October 1, 2018, 30,000 shares of restricted stock were issued to employees and were recorded at the fair value of $8.58 per share. The restricted shares vest 25% per year over a four-year vesting period and are being recognized as expense on a straight-line basis over the vesting period of the awards.

On January 25, 2018, 80,000 fully vested shares were granted to the nonemployee directors, and 229,334 stock options with a four-year vesting period were granted to employees. The shares were recorded at the fair value of $5.55 per share for a total of $444,000 and the stock options were valued using a Black Scholes model at $3.52 per option using the assumptions noted in the following table. All 229,334 stock options were unvested and had an intrinsic value of approximately $427,000 as of December 31, 2018.

| | 2018 |
|---|---|
| Expected volatility | 67.8% |
| Risk-free interest rate | 2.5% |
| Expected life | 6.25 years |
| Dividend yield | 0.0% |



The accounting guidance requires the use of a valuation model to calculate the fair value of each stock-based award. The Company uses the Black-Scholes model to estimate the fair value of stock options granted based on the following assumptions:

Expected Volatility. Expected volatility is a measure of the amount by which the Company's stock price is expected to fluctuate. Expected volatility is based on the historical daily volatility of the price of our common shares. The Company estimated the expected volatility of the stock options at grant date.

Risk-Free Interest Rate. The risk-free interest rate is based on the implied yield on U.S. Treasury zero-coupon issues with remaining terms equivalent to the expected term of our stock-based awards.

Expected Term or Life. The expected term or life of stock options granted issued represents the expected weighted average period of time from the date of grant to the estimated date that the stock option would be fully exercised. The weighted average expected option term was determined using a combination of the "simplified method" for plain vanilla options as allowed by the accounting guidance. The "simplified method" calculates the expected term as the average of the vesting term and original contractual term of the options.

The Company recognizes forfeitures as they occur rather than estimating a forfeiture rate. The reduction of stock compensation expense related to the forfeitures was approximately $39,000 and $7,000 for the years ended December 31, 2018 and 2017, respectively.

Unrecognized stock compensation expense was approximately $1,391,000 as of December 31, 2018, which will be recognized over the remaining vesting period.

The following table summarizes the Company's restricted stock activity:

| | Shares | Weighted Average Grant Date Fair Value |
|---|---|---|

| | | |
|---|---|---|
| Unvested balance at December 31, 2017 | 237,000 | $ 5.24 |
| Granted | 30,000 | 8.58 |
| Vested | (68,166) | 5.24 |
| Forfeited | (33,000) | 5.25 |
| Unvested balance at December 31, 2018 | 165,834 | $ 5.84 |

***Treasury Stock***

The Company accounts for purchases of treasury stock under the cost method with the cost of such share purchases reflected in treasury stock in the accompanying condensed balance sheet. As of December 31, 2018 and 2017, the Company had 33,454 treasury shares.

**Note 9 — Income Taxes**

The income tax provision (benefit) consisted of the following:

| | For The Years Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Current – federal | — | — |
| Current – state | — | — |
| Deferred – federal | (707,725) | (767,337) |
| Deferred – international | (40,038) | — |
| Deferred – state | (246,766) | (114,049) |
| | (994,529) | (881,386) |
| Change in valuation allowance | 994,529 | 881,386 |
| Income tax provision (benefit) | $ — | $ — |



For the years ended December 31, 2018 and December 31, 2017, the expected tax expense (benefit) based on the statutory rate is reconciled with the actual tax expense (benefit) as follows:

| | For The Years Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| U.S. federal statutory rate | (21.0)% | (35.0)% |
| State taxes, net of federal benefit | (4.8)% | (2.7)% |
| Foreign rate differential | (0.2)% | — |
| Permanent differences | 2.4% | 3.2% |
| Change in tax rates | (4.0)% | 14.4% |
| Return-to-provision adjustments | (2.2)% | — |
| Tax credits | (19.3)% | (2.1)% |
| Other | — | (1.6)% |
| Change in valuation allowance | 49.2% | 23.8% |
| **Income tax provision** (benefit) | 0.0% | 0.0% |

As of December 31, 2018 and December 31, 2017, the Company's net deferred tax asset consisted of the effects of temporary differences attributable to the following:

| | December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Net operating losses | $ 1,458,744 | $ 793,864 |
| Stock-based compensation | 122,239 | 68,730 |
| Depreciation and amortization | (97,700) | 12,473 |
| Accrued expenses and reserves | 45,106 | 77,532 |
| Tax credit | 546,592 | 155,320 |
| Other, net | 42,885 | 15,418 |
| Deferred tax asset, net | 2,117,866 | 1,123,337 |
| Valuation allowance | (2,117,866) | (1,123,337) |
| Deferred tax asset, net of valuation allowance | — | — |

The Company has federal tax net operating loss carryforwards of approximately $5,216,000 as of December 31, 2018 and state net operating loss carryforwards spread across various jurisdictions with a combined total of approximately $6,069,000 as of December 31, 2018. The net operating loss carryforwards generated prior to January 1, 2018, if not used to reduce taxable income in future periods, will begin to expire in 2029, for both federal and state tax purposes. The net operating loss carryforward generated after December 31, 2017 will never expire for federal purposes but can only reduce 80% of taxable income in future years. Additionally, the Company also has tax credit carryforwards of approximately $547,000 as of December 31, 2018. These credit carryforwards, if not used in future periods, will begin to expire in 2029.

In assessing the 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 future generation of taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and taxing strategies in making this assessment. Based on this assessment, management has established a full valuation allowance against all of the net deferred tax assets for each period, since it is more likely than not that all of the deferred tax assets will not be realized. The valuation allowance for the years ended December 31, 2018 and 2017 increased by approximately $995,000 and $881,000, respectively.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements as of December 31, 2018 and 2017. The Company does not expect any significant changes in its unrecognized tax benefits within 12 months of the reporting date. The Company has U.S. federal and certain state tax returns subject to examination by tax authorities beginning with those filed for the year ended December 31, 2014. The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the consolidated statements of operations.



On December 22, 2017, the United States enacted tax reform legislation known as the H.R.1, commonly referred to as the "Tax Cuts and Jobs Act" (the "Act"),

resulting in significant modifications to existing law. The Company has completed the accounting for the effects of the Act as of December 31, 2017. Our financial statements for the year ended December 31, 2017, reflect certain effects of the Act which includes a reduction in the corporate tax rate from 35% to 21%, as well as other changes. As a result of the changes to tax laws and tax rates under the Act, the Company incurred an incremental increase in income tax expense of approximately $562,000 during the year ended December 31, 2017, which consisted primarily of the remeasurement of deferred tax assets and liabilities from 35% to 21%. This incremental amount was offset by a change to the Company's valuation allowance resulting in no net effect.

**NOTE 10 — SUBSEQUENT EVENTS**

The Company evaluates subsequent events and transactions that occur after the balance sheet date up to the date that the financial statements were issued for potential recognition or disclosure. The Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

## Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## Item 9A. CONTROLS AND PROCEDURES

**Evaluation of Disclosure Control and Procedures**

As of December 31, 2018, the end of the period covered by this Annual Report on Form 10-K, our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer each concluded that as of December 31, 2018, the end of the period covered by this Annual Report on Form 10-K, we maintained effective disclosure controls and procedures.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our internal control over financial reporting. Our management used the updated Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission to perform this evaluation. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our internal control over financial reporting was effective as of December 31, 2018.

As an emerging growth company, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

**Changes in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting during our most recently completed quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



## Item 9B. OTHER INFORMATION

None.

## PART III.

## Item 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item will be set forth in the Proxy Statement for our 2019 Annual Meeting and is incorporated into this report by reference.

## Item 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in the Proxy Statement for our 2019 Annual Meeting and is incorporated into this report by reference.

## Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREOWNERS MATTERS

Our 2016 and 2017 Equity Incentive Plans were each approved by our stockholders. The following table provides certain information regarding the Company's equity compensation plans.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity Compensation Plans Approved by Securities Holders | 229,334 | $ 5.55 | 278,473 |
| Equity Compensation Plans Not Approved by Securities Holders | — | — | — |
| **Total** | 229,334 | $ 5.55 | 278,473 |

The other information required by this item will be set forth in the Proxy Statement for our 2019 Annual Meeting and is incorporated into this report by reference.

## Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth in the Proxy Statement for our 2019 Annual Meeting and is incorporated into this report by reference.

## Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth in the Proxy Statement for our 2019 Annual Meeting and is incorporated into this report by reference.

**PART IV**

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

The following documents are filed as part of this report

1. Financial Statements

   The Company's Financial Statements included in Part II of this Annual Report on Form 10-K are incorporated by reference into this Item 15.

2. Financial Statement Schedules

   Other schedules and exhibits are omitted because the required information either is not applicable or is shown in the financial statements or the notes thereto.

3. Exhibits Required to be Filed by Item 601 of Regulation S-K

   The Exhibit Index beginning on page 63 of this Annual Report on Form 10-K is incorporated by reference to this Item 15.

**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.

**SENSUS HEALTHCARE, INC.**

Date: March 15, 2019

/s/ Joseph C. Sardano
Joseph C. Sardano
Chief Executive Officer
(Principal Executive Officer)

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.

| Name | Title | Date |
|---|---|---|
| /s/ Joseph Sardano<br>**Joseph Sardano** | Chief Executive Officer and Chairman<br>(Principal Executive Officer) | March 15, 2019 |
| /s/ Arthur Levine<br>**Arthur Levine** | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 15, 2019 |
| /s/ John Heinrich<br>**John Heinrich** | Director | March 15, 2019 |
| /s/ William H. McCall<br>**William H. McCall** | Director | March 15, 2019 |
| /s/ Samuel O'Rear<br>**Samuel O'Rear** | Director | March 15, 2019 |
| /s/ Anthony B. Petrelli<br>**Anthony B. Petrelli** | Director | March 15, 2019 |



**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of December 12, 2011, by and between Sensus Healthcare, LLC and Sensus Healthcare, LLC – incorporated by reference to Exhibit 2.1 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 2.2 | Plan of Conversion of Sensus Healthcare, LLC – incorporated by reference to Exhibit 2.2 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 3.1 | Amended and Restated Certificate of Incorporation of Sensus Healthcare, Inc. – incorporated by reference to Exhibit 3.1 to the Company's Amendment No. 2 to Registration Statement on Form S-1 (filed 3/25/16)(No. 333-209451). |
| 3.2 | Bylaws of Sensus Healthcare, Inc. – incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |

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| 4.1 | Form of Representatives' Warrant to Purchase Units– incorporated by reference to Exhibit 4.7 of the Company's Amendment No. 4 to Registration Statement on Form S-1 (filed 5/19/16) (No. 333-209451). |
| 4.2 | Form of Indenture – incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-3 (filed 11/6/17)(No. 333-221371). |
| 4.3 | Form of Warrant Agreement, by and between Sensus Healthcare, Inc. and American Stock Transfer & Trust Company, LLC, as warrant agent, including warrant certificate – incorporated by reference to Amendment No. 3 to the Company's Registration Statement on Form S-1/A (filed 5/13/16) (No. 333-209451). |
| 10.1 | Amended and Restated Loan and Security Agreement by and between Sensus Healthcare, LLC and Silicon Valley Bank, dated as of March 12, 2013 – incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |



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| 10.2 | Default Waiver and First Amendment to Amended and Restated Loan and Security Agreement by and between Sensus Healthcare, LLC and Silicon Valley Bank, dated May 12, 2015 – incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.3 | Second Amendment and Restated Loan and Security Agreement by and between Sensus Healthcare, Inc. and Silicon Valley Bank, dated September 21, 2016 – incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q (filed 11/7/16)(No. 001-37714). |
| 10.4 | Office Lease Agreement, dated as of July 26, 2010, by and between Rexall Sundown, Inc. and Sensus Healthcare, LLC – incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.5 | Amendment to Lease, dated as of January 27, 2014, by and between Rexall Sundown, Inc. and Sensus Healthcare, LLC– incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.6 | Commercial Lease, dated as of July 7, 2016, by and between BREF 851, LLC and Sensus Healthcare, Inc. – incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q (filed 11/7/16)(No. 001-37714). |
| 10.7+ | Sensus Healthcare, Inc. 2016 Equity Incentive Plan – incorporated by reference to Exhibit 10.14 of the Company's Amendment No. 1 to Registration Statement on Form S-1 (filed 3/10/16)(No. 333-209451). |
| 10.8+ | Form of Non-Qualified Option Grant Agreement – incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.9+ | Equity Grant Agreement, dated as of July 30, 2015, by and among Arthur Levine, Sensus Healthcare, LLC and certain contributing members named therein – incorporated by reference to Exhibit 10.9 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.10+ | Employment Agreement between Sensus Healthcare, Inc. and Joseph C. Sardano – incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.11+ | Employment Agreement between Sensus Healthcare, Inc. and Kalman Fishman – incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.12+ | Employment Agreement between Sensus Healthcare, Inc. and Arthur Levine – incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.13# | Manufacturing Agreement, dated as of July 20, 2010, by and between RbM Services, LLC and Sensus Healthcare, LLC – incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 (filed 2/10/16)(No. 333-209451). |
| 10.14+ | Amendment to Equity Grant Agreement, dated as of November 16, 2016, by and among Arthur Levine, Sensus Healthcare, LLC and certain contributing members named therein. |
| 10.15 | Sensus Healthcare, Inc. 2017 Equity Incentive Plan – incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (filed 6/9/17)(No. 001-37714). |
| 10.16 | Second Amended and Restated Loan and Security Agreement – incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on From 10-Q (filed 8/4/17)(No. 001-37714). |



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| 10.17 | Second Amendment to Second Amended and Restated Loan and Security Agreement – incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on From 10-Q (filed 11/6/17)(No. 001-37714). |
| 10.18 | Third Amendment to Second Amended and Restated Loan and Security Agreement – incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on From 10-Q (filed 11/6/17)(No. 001-37714). |
| 10.19+ | Form of Restricted Stock Award Agreement incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-8 (filed 11/6/17)(No. 333-221372). |
| 10.20+ | Employment Agreement between Sensus Healthcare, Inc. and Michael Sardano – incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q (filed 5/8/18) (No. 333-209451). |
| 14.1 | Sensus Healthcare, Inc. Code of Ethics – incorporated by reference to Exhibit 14.1 of the of the Company's Amendment No. 1 to Registration Statement on Form S-1 (filed 3/10/16)(No. 333-209451). |
| 21.1 | Subsidiaries – Incorporated by reference to Exhibit 21.1 of the Company's Annual Report on Form 10-K (filed 3/10/17)(No. 001-37714). |
| 23.1* | Consent of Registered Independent Accounting Firm. |
| 31.1* | Certification of Joseph C. Sardano, Chairman and Chief Executive Officer of Sensus Healthcare, Inc., Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934. |
| 31.2* | Certification of Arthur Levine, Chief Financial Officer of Sensus Healthcare, Inc., Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934. |

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| 32.1* | Certification of Joseph C. Sardano, Chairman and Chief Executive Officer of Sensus Healthcare, Inc., Pursuant to 18 U.S.C. Section 1350. |
| 32.2* | Certification of Arthur Levine, Chief Financial Officer of Sensus Healthcare, Inc., Pursuant to 18 U.S.C. Section 1350. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |

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| + | Indicates a management contract or compensatory plan. |
| # | Portions of exhibit have been granted confidential treatment by the SEC. |
| * | Filed electronically herewith. |



EX-23.1 2 s116712_ex23-1.htm EXHIBIT 23.1

**Exhibit 23.1**

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Sensus Healthcare, Inc. on Form S-3 FILE NO. 333-221371 of our report dated March 15, 2019, with respect to our audits of the consolidated financial statements of Sensus Healthcare, Inc. as of December 31, 2018 and 2017 and for the years ended December 31, 2018 and 2017, which report is included in this Annual Report on Form 10-K of Sensus Healthcare, Inc. for the year ended December 31, 2018.

/s/ Marcum LLP

Marcum LLP
Fort Lauderdale, FL
March 15, 2019

EX-31.1 3 s116712_ex31-1.htm EXHIBIT 31.1

**Exhibit 31.1**

**Certification of CEO Pursuant to Securities Exchange Act**
**Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to**
**Section 302 of the Sarbanes-Oxley Act of 2002**

I, Joseph C. Sardano, certify that:

1. I have reviewed this annual report on Form 10-K of Sensus Healthcare, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Date: March 15, 2019

/s/ Joseph C. Sardano
Joseph C. Sardano
Chairman and Chief Executive Officer

EX-31.2 4 s116712_ex31-2.htm EXHIBIT 31.2

**Exhibit 31.2**

**Certification of CFO Pursuant to Securities Exchange Act**
**Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to**
**Section 302 of the Sarbanes-Oxley Act of 2002**

I, Arthur Levine, certify that:

1. I have reviewed this annual report on Form 10-K of Sensus Healthcare, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Date: March 15, 2019

/s/ Arthur Levine
Arthur Levine
Chief Financial Officer



EX-32.1 5 s116712_ex32-1.htm EXHIBIT 32.1

**Exhibit 32.1**

**Certification of CEO Pursuant to 18 U.S.C. Section 1350**

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned certificates that:

(1) this Annual Report for Sensus Healthcare, Inc. (the "Company") on Form 10-K for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (this "Report"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered therein.

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Joseph C. Sardano
Joseph C. Sardano

Chairman and Chief Executive Officer

March 15, 2019



EX-32.2 6 s116712_ex32-2.htm EXHIBIT 32.2

**Exhibit 32.2**

**Certification of CFO Pursuant to 18 U.S.C. Section 1350**

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned certificates that:

(1) this Annual Report for Sensus Healthcare, Inc. (the "Company") on Form 10-K for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (this "Report"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered therein.

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Arthur Levine
Arthur Levine

Chief Financial Officer

March 15, 2019